NISTIR 6086

Using Voluntary Standards in the Federal Government

Conference Summary and Viewgraphs

U.S. DEPARTMENT OF COMMERCE
Technology Administration
National Institute of Standards
and Technology
Gaithersburg, MD 20899-0001

NIST

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September 1997

U.S. DEPARTMENT OF COMMERCE
William M. Daley, Secretary

TECHNOLOGY ADMINISTRATION
Gary Bachula, Acting Under Secretary for Technology

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY
Robert E. Hebner, Acting Director

Acknowledgments

We would like to thank the following individuals for their contributions to the success of the conference: Judith Baker, Christine DeVaux, Krista J. Leuteritz, Joan Tyler and Shirley Walters. We would also like to thank Walter Leight and Maureen Breitenberg for their review of this document.

Dr. Belinda L. Collins
Office of Standards Services

ABSTRACT

Using Voluntary Standards in the Federal Government is a compilation of presentations given at a NIST-sponsored conference held on September 8, 1997. The purpose of the conference was to foster better understanding among Federal agencies of the private sector standardization process. The conference took place as part of a major effort by NIST to implement the National Technology Transfer and Advancement Act (NTTAA). The NTTAA gives NIST responsibility to coordinate standards and conformity assessment activities with other Federal agencies, state and local governments, and with the private sector.

Key Words:
conformity assessment; NTTAA; private sector; voluntary standards

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SUMMARY

On September 8, 1997, The National Institute of Standards and Technology held a day-long conference on "Using Voluntary Standards in the Federal Government" focused on successful use by Federal agencies of voluntary consensus standards developed by the private sector.

Chaired by Dr. Belinda Collins, Director of the Office of Standards Services, the conference was part of the ongoing implementation of the National Technology Transfer and Advancement Act (NTTAA). The Act (P.L. 104-113) was signed into law by the President on March 7, 1996, assigning to NIST a leadership role in coordinating standards and conformity assessment activities among federal, state and local government agencies, and with the private sector, to meet the needs of U.S. industry in the global marketplace. Collins provided background on the Act, which contains specific provisions for standards-related activities. Federal agencies must compare private sector voluntary standards used in scientific investigations, engineering, manufacturing, commerce, industry, and educational institutions with those developed by the Federal government.

After introductions and a keynote speech delivered by James Turner (Professional Staff Member, House Committee on Science), Sergio Mazza, President of the American National Standards Institute (ANSI) reviewed the generic process for developing U.S. voluntary standards. Four panels then presented examples of the successful use of voluntary standards for governmental procurement or regulatory purposes, and for meeting future national needs. Panelists described the impact of particular standards on agency goals, the process of developing the voluntary standards, and problems that had been encountered and resolved.

The conference was attended by more than 200 participants, including representatives from eight major standard developing organizations and from Federal agencies that work with the private sector to develop mutually beneficial standards, resolve policy issues, and use standards for Federal procurement or regulation. Among the Federal agencies represented were: The Consumer Product Safety Commission (CPSC), the Department of Defense (DOD), the Department of Energy (DOE), Department of Labor (DOL), the Department of Transportation (DOT), the Environmental Protection Agency (EPA), the Federal Bureau of Investigation (FBI), the Food and Drug Administration (FDA), the Federal Highway Administration (FHA), the Federal Communications Commission (FCC), the General Services Administration (GSA), the Department of Health and Human Services (HHS), the Department of Housing and Urban Development (HUD), the National Aeronautics and Space Agency (NASA), the Department of Agriculture (USDA), National Archives, U.S. Customs, U.S. Postal Service, U.S. Treasury and the National Institute of Standards and Technology.

Overall, the conference fostered better understanding among federal agencies of the private sector standardization process and paved the way for increased future collaborative efforts.

AGENDA

AGENDA

"Using Voluntary Standards in the Federal Government"

Date: **September 8, 1997** ***Location:*** **NIST, Red auditorium**

8:00 a.m. **Registration & Coffee** (*Exhibits/networking opportunities)*

8:20 a.m. **Welcome**

Dr. Robert Hebner, Acting Director of NIST

8:30 a.m. **Opening Remarks**

Dr. Peter L. M. Heydemann, Director of Technology Services

8:40 a.m. **Facilitator** (*provide background on NTTA, explain the Law*)

Dr. Belinda Collins, Director of the Office of Standards Services

9:00 a.m. **Keynote Address**

Mr. James H. Turner, Professional Staff Member, House Committee on Science

9:20 a.m. ***The ANSI Role*** **-** Sergio Mazza, ANSI President and CEO

9:40 a.m. ***Break (Exhibits/networking opportunities)***

10:00 a.m ***Regulatory Standards Panel on Health/Safety***

Moderator: Mr. Richard (Gene) Feigel, ASME Senior Vice President of Codes and Standards

Case Study #1

Speaker: Mr. Howard Hime, Chief, Office of Standards, Evaluation and Development, Department of Transportation *(DOT)*

The U.S. Coast Guard has been an active participant in codes and standards development, particularly the Boiler and Pressure Vessel Code. Mr. Hime will discuss the on-going role of the USCG in private sector standards development and the value those standards bring to their role as regulators. The Standards Development Organizations providing the forum for this case study are ASTM, ASME and NFPA.

CASE Study #2

Speaker: Mr. Richard Felder, Associate Administrator, Department of Transportation (DOT), Office of Pipeline Safety

DOT has made use of private sector standards for their gas transmission and liquid petroleum pipeline regulations since the 1960's. Mr. Felder will discuss the development of risk management standards for the pipeline industry, and how DOT is moving toward adoption of consensus standards for pipelines and liquefied petroleum gas storage. The Standards Development Organizations providing the forum for this case study are NFPA and ASME.

Case Study #3

Speaker: Mr. Gil Millman, Program Manager, Codes and Standards, Nuclear Regulatory Commission

The NRC has relied upon consensus standards to develop nuclear codes and standards for the construction and in service inspection of nuclear power plants. Mr. Millman will discuss the standards making process between a regulatory agency and a standards development organization. The Standards Development Organization providing the forum for this case study is ASME.

Case Study #4
Speaker: Colin B. Church, Consumer Product Safety Commission (CPSC)

Saving lives and reducing serious injuries is the business of the CPSC. Mr. Church will discuss how voluntary safety standards are making our homes, schools and recreation areas safer places. The Standards Development Organization providing the forum for this case study is UL.

11:05 a.m. ***Regulatory Standards Panel on Energy/Environment***

Moderator: Mary C. McKiel, Director of Standards Network, Environmental Protection Agency

Case Study #1
Speaker: Steven McNeely, Environmental Protection Agency, Office of Underground Storage Tanks

In the U.S. there are some 1,200,00 underground storage tanks that pose a risk to the environment. The EPA set a deadline of 1998 for these tanks to be upgraded or replaced. EPA and other key stakeholders (petroleum companies, environmental professionals, and others) debated the issues, searched for and developed a common solution. The Standards Development Organization providing the forum for this case study is ASTM.

Case Study #2
Speaker: Caroline B. Purdy, Program Manager for Characterization, Monitoring, and Sensor Technology Integrated Program, Department of Energy (DOE)

DOE sponsored a collection of 22 states to work together to develop solutions to environmental problems and reduce barriers to the introduction of innovative technologies into the marketplace. One successful challenge was the development of a Site Characterization Standard. The Standards Development Organization providing the forum for this case study is ASTM.

11:45 a.m. ***Question & answer session***

12:00 p.m. ***Procurement Standards Panel***

Moderator: Mr. Gregory Saunders, Deputy Director, Accession Practices, Office of the Assistant Secretary of Defense

Case Study #1
Speakers: James D. Nicolo, Director Commodity Management Group, Defense Industrial Supply Center, Department of Defense (DoD) and Bruce L. Mahone, Director of Standardization, AIA

For DoD, the primary benefits of voluntary consensus standards usage are reduced acquisition costs and removal of impediments to commercial-military integration. As a means of reducing administrative work and increasing accessibility, the Department has recommended the adoption of voluntary consensus standards. To date, approximately 7,500 voluntary consensus standards have been adopted by DoD. This case study provides details on how this approach is being used successfully for aerospace fasteners.

Case Study # 2

Speaker: Howard Bloom, Deputy Director, Manufacturing Engineering Laboratory, National Institute of Standards and Technology

Clearly, computerization has become a major driver of technology. One emerging standard relevant to computerization is the national effort called the Product Data Exchange Standard (PDES) or STEP (in the International Standards arena.) The standard is for exchange of unequivocal concepts taken bitewise and in a relatively well-confined context. PDES/STEP does this by providing both national and international agreed-upon (consensus) meaning and structure to the data when exchanged among computer systems. The development of this standard and how it is used by various industrial sectors will be the topic of this discussion. The Standards Development Organization providing the forum for this case study is the IGES/PDES Organization (IPO).

12:45 p.m. ***Question & answer session for Procurement Panel***

12:50 p.m. ***Lunch*** *(Exhibits/networking opportunities)*

2:00 p.m. ***National Strategic Standards Panel***

Moderator: **Richard Serbu, Manager, Technical Standards Program Office, Department of Energy**

Case Study #1

Speaker: Michael Schagrin, Standards Program Manager, Intelligent Transportation Systems Joint Program Office, DOT

The key to achieving widespread interoperability among the Intelligent Transportation System (ITS) services is through the implementation of robust non-proprietary standards. The U.S. Department of Transportation's (US DOT) ITS Joint Program Office is supporting an extensive, multi-year program of accelerating such standards development to strengthen and facilitate the successful deployment of ITS, with a specific near-term focus on infrastructure. The program is supporting and accelerating the existing ITS consensus-based volunteer standards processes already underway in the U.S. The standards organizations receiving funding support as part of this activity are:

- *The Society of Automotive Engineers (SAE)*
- *The Institute of Transportation Engineers (ITE)*
- *The Institute of Electrical and Electronics Engineers (IEEE)*
- *The American Association of State Highway and Transportation Officials (AASHTO)*
- *The American Society for Testing & Materials (ASTM)*

Case Study # 2

Speaker: Dr. Michael Fitzmaurice, Director, Center for Information Technology, Agency for Health Care, Policy and Research, Health and Human Services (HHS)

The Health Insurance Portability and Accountability Act of 1996 includes a provision to develop standards that will reduce the costs and administrative burdens of health care by making possible the standardized, electronic transmission of certain administrative and financial transactions, currently carried out manually on paper. This presentation will address how the Department of Health and Human Services is working with a variety of ANSI accredited voluntary standards organizations to develop needed standards. The Standards Development Organizations providing the forum for this case study are ANSI X12, ASTM, IEEE, HL7 & others.

Case Study #3

Speakers: Donald Marlowe, Director, Office of Science and Technology, Center for Devices and Radiological Health, Food and Drug Administration (FDA), and Dr. Gary Fischman, Center for Devices and Radiological Health, FDA

The Food and Drug Administration has been developing a new model for standards development within the organization . The extent of standards development efforts, the current standards development model, and a case study of how standards works at the FDA will be given. The Standards Development Organization providing the forum for this case study is ASTM.

2:45 p.m. ***Question & answer session for Strategic Standards Panel***

3:00 p.m. ***Break** (Exhibits/networking opportunities)*

3:30 p.m. ***Issues - future actions***

Dr. Belinda Collins, Director, Office of Standards Services

4:00 p.m. ***Wrapup - Adjourn***

Dr. Belinda Collins, Director, Office of Standards Services

Section 1

P.L. 104-113
Federal Use of Voluntary Standards

PL 104-113
Federal Use of Voluntary Standards

Belinda L. Collins
Office of Standards Services

Public Law Directs that:

- Federal Agencies shall rely on voluntary standards to the extent practicable for regulatory and procurement purposes
  - identify agency needs and applicable voluntary standards
  - participate in development of voluntary standards
- NIST shall coordinate with Federal, state and local agencies and with private sector on standards and conformity assessment activities
- NIST submitted Implementation Plan to Congress

Background

- NRC Report on Standards, Conformity Assessment and Trade for the 21st Century
- U.S. standards and conformity activities are decentralized, often competitive, and a mixture of public and private activities.
  - Increases product cost, time to market, wastes staff resources, and hinders exports
- Need for national infrastructures for standards and conformity assessment to support global trade

NIST Responsibilities

- Cooperate with OMB and ICSP members
  - Assist in revision of OMB Circular A-119
- Chair Interagency Committee on Standards Policy
- Provide assistance and leadership for Federal Agencies
  - Report annually on use of private sector voluntary standards, development of any new agency specific standards, and agency participation in voluntary standards activities
  - Report through OMB to Congress

New NIST Responsibilities

- Assist agencies in developing and implementing policy and procedures for using voluntary standards and participating in their development
- Identify policy issues and work through the ICSP to resolve
- Develop effective strategies for collaboration between government agencies and private sector
- Continue traditional technical and policy roles in standards and conformity assessment

Federal Agencies

- ICSP now intensifying coordination
- Agencies to identify specific issues related to use of voluntary standards and participation in process
  - Implement a strategic standards policy for use of voluntary standards
  - Develop internal processes for committing resources and staff, as well as monitoring policy issues
- NIST with ICSP to develop procedures for coordination within and among agencies

Federal Agencies and NIST will:

- Work with ANSI and standards developing organizations (SDOs) to address:
  - proliferation and overlap of standards
  - speed of standards development
  - effective use of standards by Federal agencies
- Work on policies for licensing standards
- Develop procedures for timely notification to Federal agencies of proposed new standards
- Develop mechanisms for coordinating with ANSI and other SDOs on international standards issues
- Enhance collaborative efforts on standards and conformity assessment

NIST Activities

- Work with state and local agencies to develop procedures for implementing standards and conformity assessment activities
- Develop strategies for coordination with Federal and private sector activities
- Work with representatives of building Code organizations to develop policies for standards and conformity assessment for Federal and local use

Conformity Assessment

- Includes product certification, accreditation of testing and calibration laboratories, and management system registration (quality and environment)
- U.S. must develop national strategies for coordinated systems for conformity assessment
- NIST will perform policy analysis of costs of duplication to government agencies and industry
- NIST will work with private sector conformity assessment bodies to obtain international acceptance
- All must work together to facilitate goal of one product, one standard, and one test, with worldwide acceptance

Laboratory Accreditation

- NIST working with private sector and other government agencies to establish infrastructure for coordinating activities in laboratory accreditation
  - Successful Public Forum on National Council for Laboratory Accreditation (NACLA) on Jan 7, 1997
  - Consensus on structural approach for NACLA
- NIST will continue National Voluntary Laboratory Accreditation Program
  - Accredit calibration laboratories to ensure necessary traceability to national standards
  - Accredit testing laboratories as mandated by Congress or requested by other Federal Agencies

Management System Standards

- Agencies to work through Government Industry Quality Liaison Panel (GIQLP) to ensure use of ONE quality system per supplier to the Federal government
- Develop procedures to recognize competence of each others' quality system audits

Conclusions - NIST Policy Activities

- NIST is implementing Plan to increase coordination among Federal agencies
  - Provide assistance in use of voluntary standards
- Coordinating activities with ANSI, SDOs, Federal, state and local agencies to build workable systems for standards and conformity assessment to meet the needs of U.S. industry in a global market

Conclusions - Continued
NIST Policy Activities

- Lead ICSP as a viable and effective forum for coordinating Federal efforts, and for encouraging agency use of voluntary standards
- Work effectively with state and local authorities
- Work vigorously to achieve the goal of national systems for conformity assessment that will be accepted domestically and internationally

Planned Collaborative Activities

- Open Forum on Laboratory Accreditation
- Workshop on effective Federal participation in and use of standards
- Training opportunities on process and procedures
- Policy discussions in ICSP on key issues
- Continuing support for GIQLP activities
- Continuing support for task forces on Federal uses of ISO 14000, 9000, laboratory accreditation, information resources, and strategic standards management
- Continue to solicit ideas for cooperation and collaboration between public and private sector

Section 2

The ANSI Role

VALUE AS A NATIONAL ACCREDITOR

- Accredit National Standards developers
- Accredit Conformity Assessment Programs
- Integrity of US International participation

ANSI PARTICIPATION AT IEC (THROUGH USNC)

- IEC - Geneva, Switzerland
  - 53 National Committees (Member Countries)
- US National Committee
  - one of 5 permanent members of the council board of 15
  - participates in 89% of Technical Committees
  - assigned Secretariats for 16% of TC Secretariats
  - Current president of IEC from the USA

GOVERNMENT BENEFITS FROM ANSI STANDARDS

- Lower costs
  - Procurement
  - Regulatory
- Increased
  - US competitiveness
  - Employment
  - Economic growth
- Private sector cooperation
- WTO compliance
- Legislative compliance

US INTERNATIONAL PARTICIPATION

- Accredit ISO technical advisory groups (TAGs)
- Appoint IEC technical advisors (TAs)
- Delegate TAG and US held international secretariat administration

ANSI VISION

GLOBAL COMPETITIVENESS

AND

ENHANCED QUALITY OF LIFE

WHAT IS THE "ANSI" FEDERATION?

- Public/Private sector partnership since 1918
- 1000+ Member Companies:
  - Revenues of $1.2+ trillion
- 280+ Professional, Trade, Educational, Consumer, and Labor institutions
- 30+ Government agencies

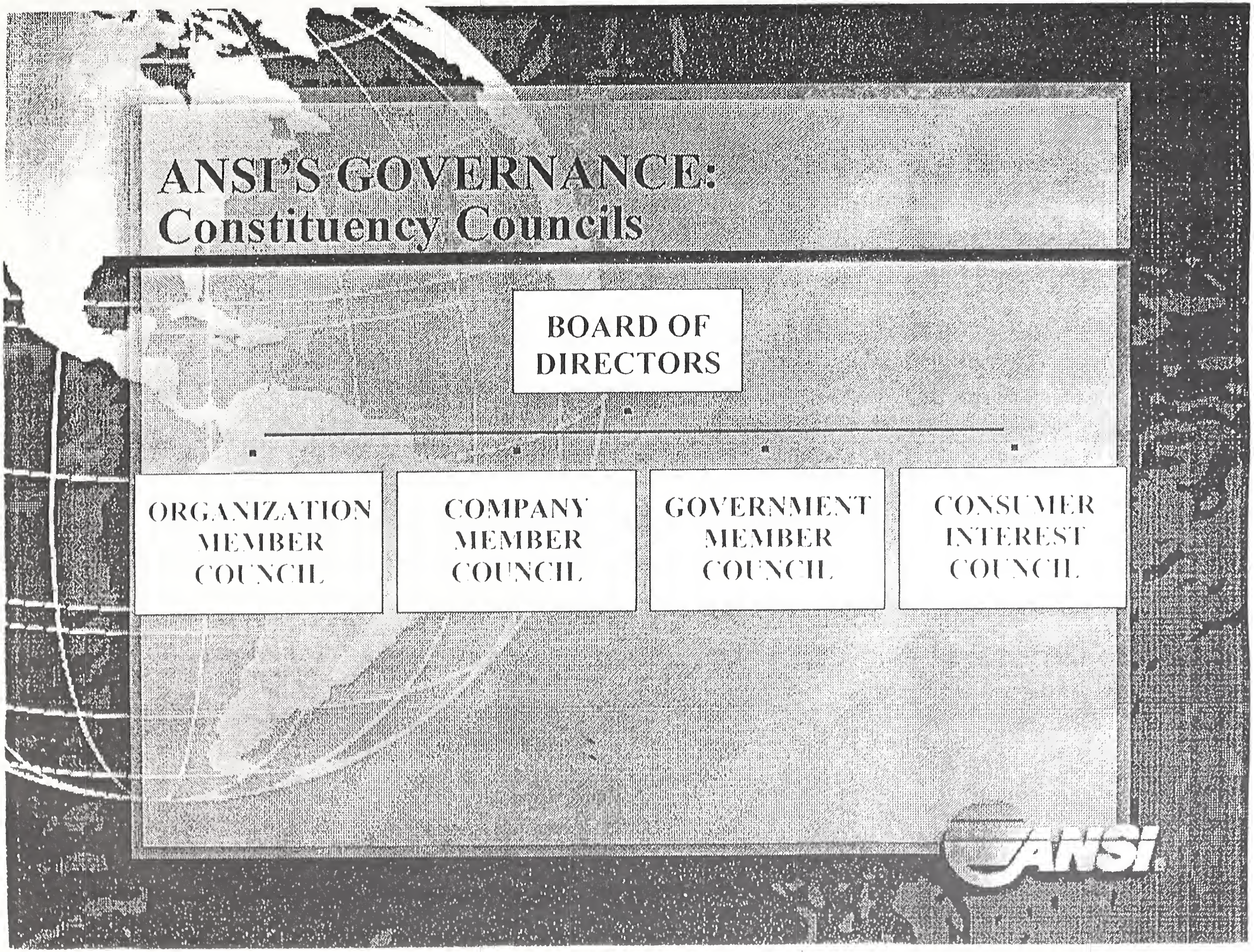
WHY HAVE AN ANSI?

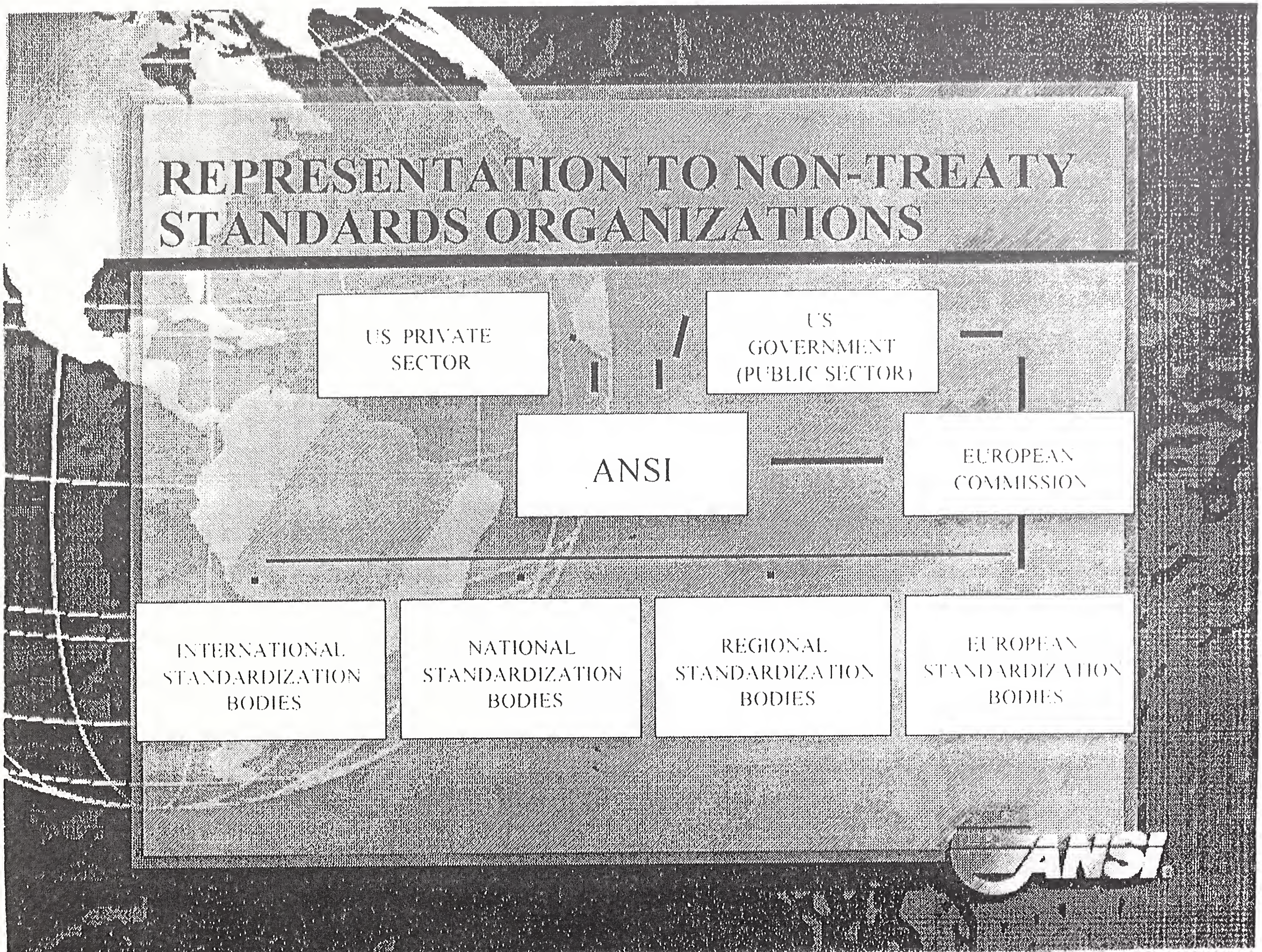
- A focal point for national standardization policy
  - Technology and policy goals
  - Quality of life issues
  - Economic growth
- Leadership in international standardization is crucial to US. competitiveness

ANSI's VALUE

- Policy forum
- Accreditor
- Source of information

ANSI


ANSI'S GOVERNANCE:
Constituency Councils
BOARD OF DIRECTORS
ORGANIZATION MEMBER COUNCIL
COMPANY MEMBER COUNCIL
GOVERNMENT MEMBER COUNCIL
CONSUMER INTEREST COUNCIL
ANSI


REPRESENTATION TO NON-TREATY STANDARDS ORGANIZATIONS
US PRIVATE SECTOR
US GOVERNMENT (PUBLIC SECTOR)
ANSI
EUROPEAN COMMISSION
INTERNATIONAL STANDARDIZATION BODIES
NATIONAL STANDARDIZATION BODIES
REGIONAL STANDARDIZATION BODIES
EUROPEAN STANDARDIZATION BODIES
ANSI

ANSI'S PARTNERSHIP WITH US GOV'T ON STANDARDS AND TRADE

ANSI	US GOV'T
◆ ISO & IEC	WTO
◆ COPANT	FTAA
◆ PASC	APEC
◆ CEN/CENELEC/ETSI	TABD
◆ EOTC	US-EU MRAs

ANSI PARTICIPATION AT ISO

- ISO – Geneva, Switzerland
  - 120 Member countries
- ANSI one of
  - 5 permanent members to the Council of 18
  - 4 permanent members to the Technical Management Board of 12
- ANSI and its members
  - participate in 74% of Technical Committees
  - administer 16% of TC Secretariats

Section 3

Regulatory Standards Panel on Health and Safety

The Importance of STANDARDS To The U.S. Coast Guard

Mr. Howard Hime

Standards Evaluation and Development Office
U. S. Coast Guard

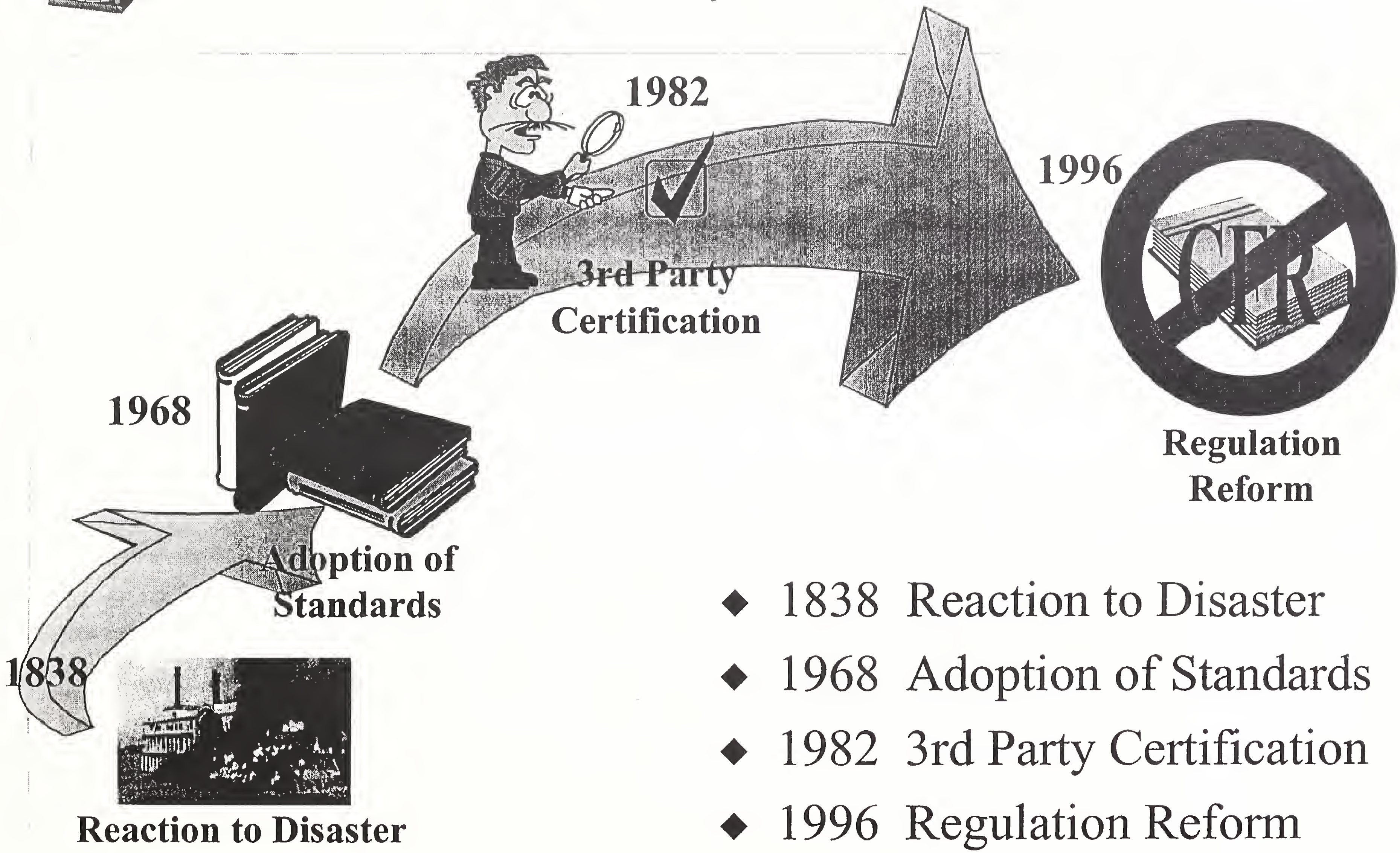
❖ Standards Policy

"Committed to developing nationally and internationally recognized standards as a means to improve maritime safety and marine environmental protection, and to promote an internationally competitive U.S. maritime industry"

VADM HENN

200 Years Protecting Life and Property at Sea

Evolution of Regs



- 1838 Reaction to Disaster
- 1968 Adoption of Standards
- 1982 3rd Party Certification
- 1996 Regulation Reform

Role of Government in Standards Development

- Raise issues of public interest
- Act as a Catalyst
- Provide balance

Benefits

- Reduce cost of compliance
- Keep pace with technology
- Planning ahead to prevent disaster
- Saves resources

❖ GOAL 1:

Develope a comprehensive set of nationally recognized, internationally compatible standards through active participation in national standards organizations

❖ GOAL 2:

Develope a comprehensive set of internationally recognized standards through active participation in IMO, ISO, IEC.......

❖ GOAL 3:

Improve U.S. competitivness by removing regulatory and other barriers that impede productivity and the free flow of commerce.

Questions?

Slide 1 The Importance of Standards to the CG

THANK YOU FOR GIVING ME THE OPPORTUNITY TO SPEAK WITH YOU TODAY ABOUT MY FAVORITE SUBJECT - STANDARDS AND THEIR IMPORTANCE TO THE COAST GUARD. STANDARDS ARE A KEY ELEMENT OF THE COAST GUARD'S STRATEGIC PLAN FOR MARITIME REGULATORY REFORM. LET ME STATE FROM THE OUTSET--THE CG TAKES A PROACTIVE POSITION REGARDING STANDARDS.

THIS POSITION WAS REAFFIRMED WHEN VADM HENN SIGNED A COMDTINST OUTLINING THE POLICY AND GOALS OF THE STDS PROGRAM FOR OUR MARINE SAFETY AND ENVIRONMENTAL PROTECTION PROGRAMS.

Slide 2 Policy

IN THIS COMDTINST, VADM HENN STATES:

THE USCG IS COMMITTED TO DEVELOPING NATIONALLY AND INTERNATIONALLY RECOGNIZED STANDARDS AS A MEANS TO IMPROVE MARITIME SAFETY AND MARINE ENVIRONMENTAL PROTECTION, AND TO PROMOTE AN INTERNATIONALLY COMPETITIVE U.S. MARITIME INDUSTRY.

THE COAST GUARD WILL CONTINUE TO STRIVE FOR A SAFE MERCHANT MARINE. HOWEVER, SAFETY MUST BE COST EFFECTIVE. IN DEVELOPING STANDARDS, OUR GOAL IS NOT ONLY TO INSURE SAFETY BUT TO ENSURE THAT THE STANDARDS DEVELOPED DO NOT PUT U.S. INDUSTRY AT A COMPETITIVE DISADVANTAGE.

Slide 3 200 years protecting life and property at sea

FOR OVER TWO CENTURIES THE COAST GUARD HAS BEEN RESPONSIBLE FOR THE PROTECTION OF LIFE AND PROPERTY AT SEA. THE USCG IS CHARGED WITH DIRECTING A COORDINATED FEDERAL PROGRAM FOR COMMERCIAL VESSEL SAFETY, PORT SAFETY, SECURITY, AND ENVIRONMENTAL PROTECTION. IN ORDER TO MEET THIS MANDATE THE COAST GUARD IS RESPONSIBLE FOR, ENFORCING APPLICABLE FEDERAL LAWS, DEVELOPING REGULATIONS NECESSARY FOR IMPLEMENTING THESE LAWS, NEGOTIATING AND ENFORCING INTERNATIONAL TREATIES, AND REPRESENTING THE UNITED STATES AND COAST GUARD INTERESTS IN NATIONAL AND INTERNATIONAL FORA.

Slide 4 Evolution of Regs

HISTORICALLY, THE REGULATORY PROCESS FOR MARINE SAFETY HAS BEEN CHARACTERIZED BY RESPONSE TO DISASTER. THE ADVENT OF STEAM PROPULSION IN THE EARLY 1800'S BROUGHT NUMEROUS SHIPBOARD BOILER EXPLOSIONS WITH TRAGIC LOSS OF LIFE. WITH PUBLIC CONCERN AT A HIGH LEVEL, CONGRESS TOOK ACTION BY PASSING THE STEAMBOAT INSPECTION ACT OF 1838 AND A SERIES OF OTHER LAWS WHICH RESULTED IN REGULATIONS AIMED AT REDUCING THE NUMBER OF SHIPBOARD EXPLOSIONS AND RESULTANT FATALITITES. THE SINKING OF THE TITANIC WITH ITS HEAVY LOSS OF LIFE POINTED OUT THE NEED FOR IMPROVED LIFESAVING CAPABILITIES AND IMPROVED STABILITY AND WATERTIGHT SUBDIVISION REQUIREMENTS. AGAIN, PUBLIC CONCERN STIMULATED CONGRESSIONAL ACTION WHICH RESULTED IN ADDITIONAL REGULATIONS. THE BURNING OF THE MORRO CASTLE, AGAIN WITH SIGNIFICANT LOSS OF LIFE, BROUGHT ABOUT IMPROVED FIRE PROTECTION REGULATIONS.

EACH OF THESE MARINE DISASTERS RESULTED IN THE PUBLICATION OF COMPRESHENSIVE REGULATIONS TO ADDRESS THE HAZARD AND MINIMIZE ITS RECURRENCE.

EARLIER REGULATORY EFFORTS WERE VERY DETAILED, AS THE VOLUNTARY STANDARDS MOVEMENT HAD ONLY BEGUN TO DEVELOP. IN THE ABSENCE OF A BROAD BASE OF INDUSTRY GENERATED STANDARDS, EXTENSIVE AND DETAILED REGULATIONS WERE DRAFTED AND ENFORCED. THE EXPANSION OF TRADE HORIZONS AND VARIATIONS IN

THE SAFETY STANDARDS IMPOSED BY JURISDICATIONS HELPED ADVANCE THE CONCEPT OF VOLUNTARY STANDARDIZATION. AS THE CONCEPT EVOLVED, MANY OF THESE VOLUNTARY STANDARDS GAINED ACCEPTANCE AS "NATIONAL" STANDARDS AND BECAME SUITABLE FOR INCORPORATION IN FEDERAL REGULATIONS. IN OTHER CASES, EXISTING DETAILED REGULATIONS FORMED THE BASIS FOR DEVELOPING A VOLUNTARY STANDARD.

IN EARLIER EFFORTS TO INCORPORATE VOLUNTARY STANDARDS, ADMINISTRATIVE PROCEDURES DICTATED THAT THEY BE REPRODUCED IN PART OR IN FULL AS REGULATIONS. IT WAS NOT UNTIL 1968 THAT THE CONCEPT OF INCORPORATION BY REFERENCE, WHERE A VOLUNTARY STANDARD IS INVOKED IN THE REGULATIONS AND IDENTIFIED ONLY BY NAME AND EDITION, ENABLED US TO REALIZE THE FULL BENEFIT OF USING NON-GOVENMENT STANDARDS.

EMPLOYING THIS METHOD WE ADOPTED WELL OVER 100 INDUSTRY STANDARDS IN 1968 AND CONTINUED TO ADD MORE EACH YEAR. WHILE WE ACCEPTED CERTIFYING MARKS FOR MANY PIPE AND ELECTRICAL COMPONENTS, WE RETAINED SHOP INSPECTION AND PLAN APPROVAL FOR MANY OTHERS, SUCH AS BOILERS AND PRESSURE VESSELS. IT WAS HARD FOR US TO GIVE UP PAST MEMORIES OF THE TRAGIC ACCIDENTS AND THE RESPONSIBILITIES ENTRUSTED TO US BY THE PUBLIC. HOWEVER, OVER THE ENSUING YEARS WE BECAME MORE INVOLVED WITH THE STANDARDS COMMITTEES, SUCH AS THE ASME B&PVC. WITH EACH

COMMITTEE WE LENT OUR EXPERIENCE IN THE FIELD OF MARINE SAFETY, ENSURING THAT THE ASSOCIATED CONCERNS ARE TAKEN INTO ACCOUNT. IN ADDITION, WE GREW MORE FAMILIAR AND CONFIDENT WITH THE DEVELOPMENT AND OPERATION OF THE STANDARDS AND BEGAN REPLACING COAST GUARD PLAN APPROVAL AND SHOP INSPECTION WITH 3RD PARTY CERTIFICATION. OUR 1ST MAJOR EFFORT CAME IN 1982 WHEN WE ADOPTED THE ASME CODE SYMBOL STAMP.

FROM 1968 TO 1995 ALL OF THE STANDARDS WE ADOPTED WERE AMERICAN NATIONAL STANDARDS. THREE YEARS AGO WE BEGAN AN EFFORT KNOWN AS REGULATORY REFORM TO LOOK AT OUR REGULATIONS, ELIMINATE THOSE THAT WERE OUTDATED OR INEFFICIENT, AND ADOPT INTERNATIONAL STANDARDS WHERE POSSIBLE. RECENTLY WE REVISED OUR ELECTRICAL REGULATIONS ADOPTING 86 NEW STANDARDS INCLUDING 32 IEC AND 12 CEN

Slide 5 Role of Govt

WHILE THE ADOPTION OF INDUSTRY STANDARDS ENABLES THE COAST GUARD TO FULFILL ITS REGULATORY FUNCTIONS MORE EFFICIENTLY, THIS CAPABILITY WOULD BE USELESS WITHOUT THE EXISTENCE OF MEANINGFUL STANDARDS. RECOGNIZING THIS REALITY EARLY ON, THE COAST GUARD AGGRESSIVELY PURSUED MEMBERSHIP ON A FULL RANGE OF STANDARDS-ORGANIZATIONS. TODAY WE SUPPORT ABOUT 30 NON-GOVERNMENT ORGANIZATIONS AND ACTIVELY PARTICIPATE ON OVER 100 STANDARDS-COMMITTEES. THIS ACTIVE PARTICIPATION ENABLES US TO RAISE GENUINE ISSUES OF PUBLIC SAFETY AND PRESERVATION OF THE MARINE ENVIRONMENT. ADDITIONALLY, WHERE INDUSTRY HAS NOT ESTABLISHED SUITABLE SAFETY REQUIREMENTS, WE CATALYZE THEIR DEVELOPMENT.

Slide 6 Benefits

BECOMING AN INTEGRAL PART IN THIS PROCESS HAS ENABLED THE COAST GUARD TO AVOID DRAFTING UNNECESSARILY DETAILED REGULATIONS AND IN SOME CASES AVOIDING REGULATION COMPLETELY. IT HAS ALSO HELPED US TO EVOLVE FROM A REGULATORY PROCESS WHICH REACTS TO DISASTER TO A MORE ORDERLY PROCESS WHICH RECOGNIZES TECHNICAL INNOVATION AND PROGRESSIVE IDEAS AIMED AT PREVENTING DISASTER.

TO DATE WE CURRENTLY ADOPT APPROXIMATELY 300 INDUSTRY STANDARDS, SAVING OVER 25,000 PAGES OF FEDERAL REGULATIONS AND THE ASSOCIATED REGULATION MAINTENACE, WHILE SPECIFYING STANDARDS ALREADY FAMILIAR TO THE INDUSTRY REGULATED.

WE ESTIMATE THAT OUR PARTICIPATION ON STANDARDS COMMITTEES SAVES US OVER $1M ANNUALLY AND INCREASES OUR INSPECTION AND TECHNICAL FORCE 100 TIMES.

THIS LAST POINT IS EXTREMELY SIGNIFICANT. WHEN I GO TO A COMMITTEE MEETING I'VE GOT 30, 60 OR 100 EXPERTS WORKING FOR ME , DEVELOPING MY REGULATIONS.

WHEN WE ADOPT CERTIFYING MARKS , EG, ASME'S CODE SYMBOL STAMP OR UL'S MARK, I'VE GOT 100'S OF INSPECTORS AND LAB TECHNICIANS WORKING FOR ME

Slide 7 Goal 1

ONE OF THE GOALS OF OUR STDS PROGRAM IS TO **DEVELOP A COMPREHENSIVE SET OF NATIONALLY RECOGNIZED, INTERNATIONALLY COMPATIBLE STANDARDS THROUGH ACTIVE PARTICIPATION IN NATIONAL STANDARDS ORGANIZATIONS.**

WITH THE HELP OF INDUSTRY WE HAVE DEVELOPED A NUMBER OF STANDARDS TO MEET REQUIREMENTS OF INT'L CONVENTIONS, SUCH AS SOLAS AND MARPOL, e.g. AT ASTM WE FORMED A WG TO DEVELOP STDS FOR SHIPBOARD INCINERATORS. WE GOT REPS FROM JAPAN & EUROPE TO PARTICIPATE TO ENSURE THE STANDARD'S INT'L ACCEPTANCE. THIS ASTM STD WAS DEVELOPED IN 2 SHORT YEARS AND IS NOW ADOPTED BY IMO AND ISO. OTHER STDS INCL WATERTIGHT DOORS AND PLASTIC PIPE . IN ADDITION, WE ARE CURRENTLY REDRAFTING A NUMBER OF ASTM STANDARDS TO PROPOSE AS INTERNATIONAL ISO STANDARDS.

WE HAVE SPEARHEADED AN EFFORT TO GET ASME TO ADOPT IN THEIR CODES FOREIGN MATERIAL STANDARDS SUCH AS JIS, DIN, AND ISO. THIS WILL FURTHER ENHANCE THE INT'L ACCEPTANCE OF ASME CODES AND STDS AND IMPROVE THE COMPETIVENESS OF US SHIPPING.

AT NFPA WE HAVE ESTABLISHED A NEW COMMITTEE TO ADDRESS MARINE RELATED FIRE PROTECTION ISSUES. THE NEED FOR THIS COMMITTEE BECAME APPARENT WITH THE ADVENT OF THE RIVERBOAT GAMING INDUSTRY. OUR REGS WERE NOT GEARED FOR THESE HIGH PASSENGER DENSITY VESSELS WITH LARGE OPEN SPACES AND ATRIUMS EXTENDING THROUGH MULTIPLE DECKS. OUR GOAL IS TO DEVELOP A LIFE SAFETY CODE FOR SHIPS PATTERNED AFTER NFPA'S LIFE SAFETY CODE FOR BUILDINGS. THIS WILL GIVE THE DESIGNER MORE FLEXIBILITY BY PROVIDING A NUMBER OF DESIGN OPTIONS AND TRADE-OFFS.

Slide 8 Goal 2

ANOTHER GOAL OF OUR STANDARDS PROGRAM IS:

TO DEVELOP A COMPREHENSIVE SET OF INTERNATIONALLY RECOGNIZED STANDARDS THROUGH ACTIVE PARTICIPATION IN IMO AND OTHER INTERNATIONAL STANDARDS MAKING ORGANIZATIONS SUCH AS ISO AND IEC.

WE ARE CONTINUING TO WORK AT IMO TO "LEVEL THE INTERNATIONAL PLAYING FIELD." THIS IS BEING DONE BY RAISING INTERNATIONAL SAFETY REQUIREMENTS TO THE LEVEL EXPECTED BY THE AMERICAN PUBLIC. IN ADDITION, WE ARE WORKING TO ELIMINATE AMBIGUOUS REQUIREMENTS IN SOLAS SUCH AS PHRASES LIKE "SUBJECT TO THE SATISFACTION OF THE ADMINISTRATION." THESE PHRASES LEAD TO A WIDE VARIETY OF INTERPRETATION AND ENFORCEMENT; STANDARDS ARE AN EFFECTIVE WAY TO ELIMINATE THESE AMBIGUOUS PHRASES. IN THIS REGARD, WE ARE WORKING TO INCREASE IMO'S ACCEPTANCE OF STANDARDS DEVELOPED BY OTHER ORGANIZATIONS. A GOOD EXAMPLE IS IMO'S ACCEPTANCE OF THE SHIPBOARD INCINERATOR STANDARD DEVELOPED BY ASTM AND EMBRACED BY ISO. AT ISO WE HAVE A NUMBER OF STANDARDS UNDER DEVELOPMENT REQUESTED BY IMO. MANY OF THESE STANDARDS ARE BEING DEVELOPED BY SUBCOMMITTEES LED BY THE UNITED STATES. THESE STANDARDS WILL FILL THE GAP, IMPROVE SAFETY, AND LEVEL THE PLAYING FIELD FOR ALL.

Slide 9 Goal 3

AND LAST BUT NOT LEAST OUR GOAL IS TO **IMPROVE COMPETITIVENESS OF THE U.S. MARITIME INDUSTRY BY REMOVING REGULATORY AND OTHER BARRIERS THAT IMPEDE PRODUCTIVITY AND A FREE FLOW OF COMMERCE.**

THIS GOAL IS BEING ACHIEVED BY USING INTERNATIONALLY AND NATIONALLY AGREED UPON STANDARDS AS ALTERNATIVES TO REGULATIONS AND BY PROMOTING DEVELOPMENT OF PERFORMANCE BASED STANDARDS RATHER THAN DETAILED SPECIFICATIONS AS THE MEANS OF COMPLIANCE. RECENTLY WE PUBLISHED SWEEPING REG REFORM CHANGES TO OUR ELECTRICAL ENGINEERING REGS. WE ADOPTED 86 NEW STANDARDS INCLUDING 32 IEC AND 12 CEN!

IN ADDITION, WE ARE EMBARKING ON THE USE OF RISK-BASED METHODOLOGIES TO DETERMINE THE LEVEL AND DEGREE OF STANDARDIZATION NEEDED. USING RISK BASED METHODS IN A TOP DOWN SYSTEMS ENGINEERING APPROACH WE CAN DETERMINE THE RELATIVE SAFETY HAZARDS AND DETERMINE THE EFFECTIVE LEVEL OF STANDARDIZATION NEEDED. USING RISK BASED METHODS ON SPECIALLY DESIGNED CARGO VESSELS,WE SAVED OVER $2M PER VESSEL.

IN SUMMARY, THE COAST GUARD IS COMMITTED TO DEVELOPING THE STANDARDS NEEDED TO IMPROVE SAFETY, PROTECT THE ENVIRONMENT , AND REDUCE THE COST OF GOVERNMENT REGULATIONS.

Richard Felder

Office of Pipeline Safety
Department of Transportation

OPS MEMBERSHIP ON STANDARDS GROUPS

- ***AGA/ANSI****/Gas Piping Technology Committee*
- ***API****/committee on Refinery Equipment Subcommitte on Pressure Vessels and Tanks*
- ***API****/API 6D Specification for Pipeline Valves*
- ***API 5L****/Specification for Line Pipe*
- ***API 1104****/Joint API-AGA Standards for Welding Pipe Lines and Related Facilities*
- ***ASME 31.4****/American Society of Mechanical Engineers (Liquid)*
- ***ASME 31.8****/American Society of Mechanical Engineers (GAS)*
- ***ASTM F-17****/Plastic Pipe*
- ***ASTM****/Committee A-1 on Steel, Stainless Steel, and Related Alloys, Subcommittee A01.09 on Pipe*
- ***ASTM D 2513*** *Standards Specification for Thermoplastic Gas Pressure Pipeline System*

OPS MEMBERSHIP ON STANDARDS GROUPS

- ***NACE/T-10** Committee on Underground Corrosion (Ondak also a Member of NACE Board of Directors and Govenrment Liaison to Public Affairs Committee)*
- ***NFPA 58** Standard for the Storage and Handling of Liquefied Petroleum Gases*
- ***NFPA 59** Standard for the Storage and Handling of Liquefied Petroleum Gases at Utility Gas Plants*

UNITED STATES NUCLEAR REGULATORY COMMISSION

NRC USE OF ASME CODES AND STANDARDS

September 8, 1997

Gilbert C. Millman
Program Manager, Codes and Standards
U.S. Nuclear Regulatory Commission

THE NRC

AN INDEPENDENT REGULATORY AGENCY

- *Authority* Includes, Atomic Energy Act of 1954, as amended; Energy Reorganization Act of 1974, as amended
- *Mission* Regulate civilian use of nuclear materials to ensure adequate protection of the public health and safety, common defense and security, and the environment
- *Scope* To regulate:
  - Commercial nuclear power reactors
  - Nonpower research, test, and training reactors
  - Fuel cycle facilities
  - Medical, academic, industrial uses of materials
  - Transport, storage, and disposal of nuclear materials and waste

GOOD REGULATION AND STANDARDS WRITING

COMMON PRINCIPLES

- *Independence* — Ethical performance, objective assessment of all information
- *Openness* — Business conducted publicly and candidly
- *Efficiency* — Technical and managerial excellence, with due consideration of resources
- *Clarity* — Coherent, logical, practical
- *Reliability* — Best available knowledge from research and operational experience

ASME CONSENSUS STANDARDS

WHY THEY ARE IMPORTANT TO NRC

- Complement NRC's broad General Design Criteria
- Form a basis for NRC requirements and guidance in design, construction, operation, inspection, testing, modification and repairs of mechanical and electrical components, and large civil structures
- Incorporate many years of accepted good engineering practice and reflect state-of-the-art technology

NRC PARTICIPATION IN CONSENSUS PROCESS

BENEFIT TO NRC

- Efficient use of NRC resources
- Interaction results in higher probability of better, more practical standards
- Wider, more ready acceptance by public, industry, and government agencies
- Standards not endorsed in full represent a good basis for limited exceptions

NRC PARTICIPATION IN CONSENSUS PROCESS

STAFF CONSIDERATIONS

- Voluntary nature of process
- Importance of interaction and feedback
- Impact of endorsement process

NRC USE OF ASME CONSENSUS STANDARDS

SOME IMPORTANT MILESTONES

- 1971 AEC mandates use of ASME Section III (construction) and Section XI (inservice inspection)
- 1982 OMB Circular A-119 first issued
- 1982 NRC establishes Committee for Review of Generic Requirements (CRGR); final Backfit Rule (1985)
- 1986 NRC recognizes ASME Accreditation Program
- 1990 ASME issues Operation and Maintenance Code
- 1996 ASME mandates use of ASME Section XI rules for containment inspections

STAFF PARTICIPATION ON SDOS

STANDARDS DEVELOPMENT ORGANIZATIONS	Committees
• American Society of Mechanical Engineers	47
• American Nuclear Society	39
• Institute of Electrical and Electronics Engineers	26
• Health Physics Society	12
• American Society of Testing and Materials	11
• Institute of Nuclear Materials Management	6
• American National Standards Institute	5
• American Concrete Institute	4
• American Society of Civil Engineers	4
• Other	12

STAFF PARTICIPATION ACROSS NRC OFFICES

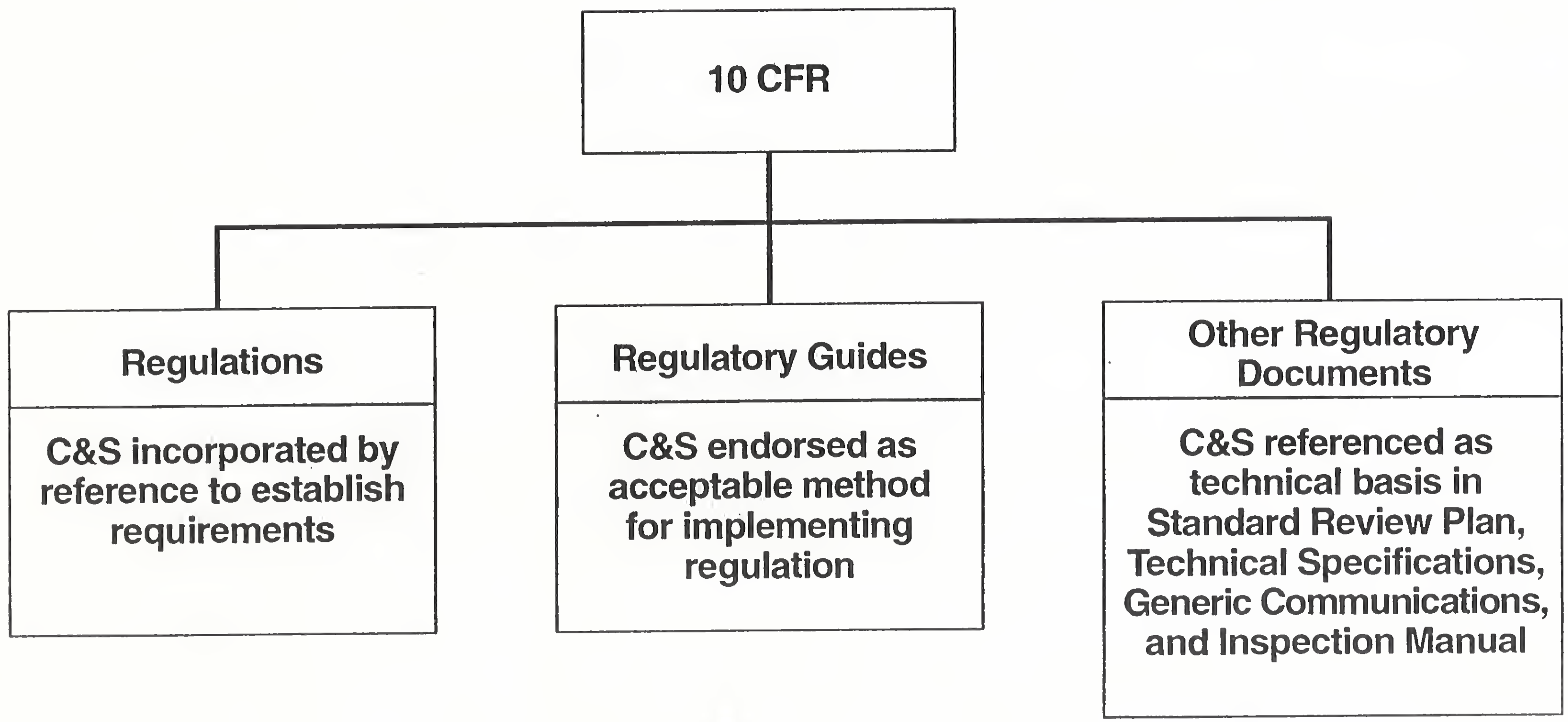
OFFICE	STAFF
• Nuclear Reactor Regulation	71
• Nuclear Materials Security and Safeguards	21
• Nuclear Regulatory Research	34
• Analysis and Evaluation of Operational Data	6
• Regions	9
• Controller	1

REGULATORY FRAMEWORK

ENDORSEMENT OF CODES AND STANDARDS

- Public Law 104-113, “National Technology Transfer and Advancement Act of 1995”
- OMB Circular A-119, “Federal Participation in the Development and Use of Voluntary Standards”
- Regulations, primarily 10 CFR § 50.55a, “Codes and standards”
- Regulatory guides and other regulatory documents

INTEGRATION OF CODES AND STANDARDS INTO THE REGULATORY PROCESS

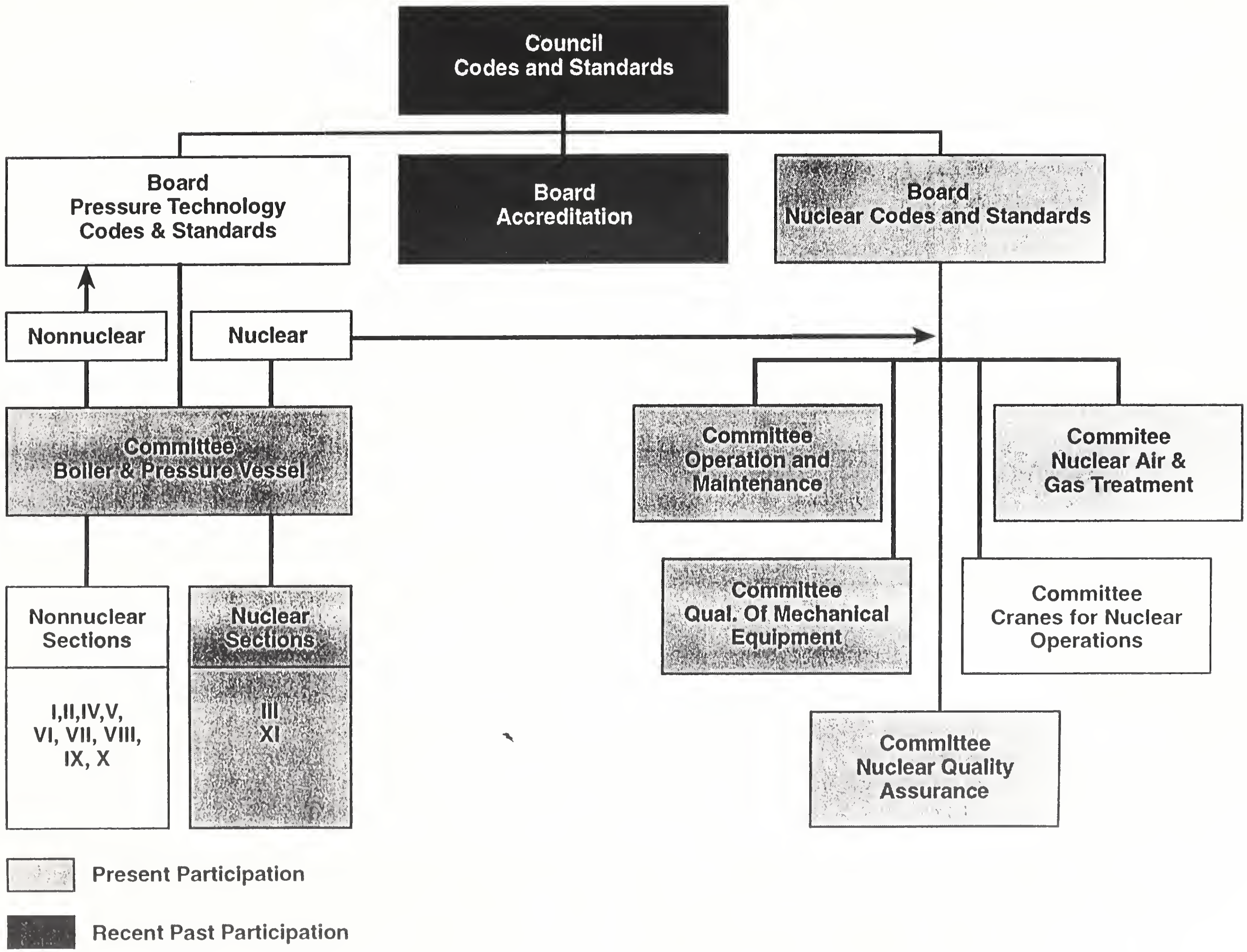


10 CFR § 50.55A

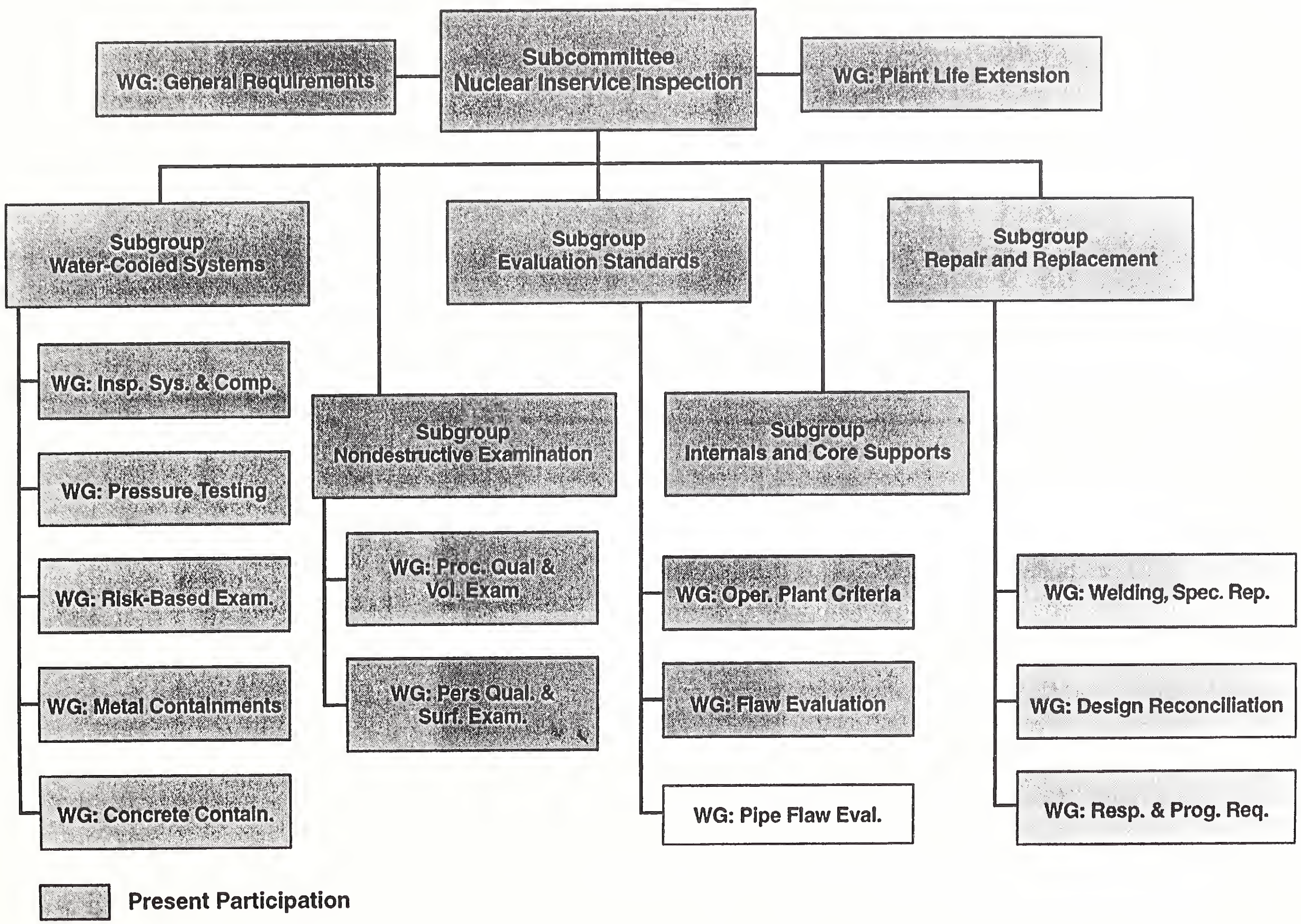
SCOPE

- Incorporates, by reference, ASME Section III and Section XI
- May impose NRC limitations and modifications
- Requires 120-month update of inservice inspection (ISI) and inservice testing (IST) programs
- Endorses use of ASME code cases via three referenced regulatory guides
- Incorporates by reference IEEE Standard on reactor protection systems

NRC STAFF ON ASME COMMITTEES



NRC STAFF ON ASME SECTION XI



NRC INITIATIVES

STRATEGIC ASSESSMENT AND REBASELINING

- Foundation for future direction and decision making
  - Initiated (1995)
- Direction Setting Issues (DSIs) address major aspects of NRC functions
- DSI-13, "Role of Industry" encompasses use of standards

10 CFR § 50.55A

- Amend to update references to ASME Section III and Section XI, and for the first time endorse ASME Operation and Maintenance (OM) Code for inservice testing

DSI-13, "ROLE OF INDUSTRY"

COMMISSION FINAL DECISION

- Streamline and simplify NRC's internal process for endorsing codes and standards
- Establish internal performance indicators to ensure timely update of regulations and regulatory guides
- Determine degree to which current backfit rule implementation impedes the adoption of updated codes and standards
- Implement Public Law 104-113 and supporting OMB Circular A-119

THE CHALLENGE

MAINTAIN CREDIBLE CONSENSUS PROCESS — JOINT SDO AND USER RESPONSIBILITY

- Achieve consensus
- Know user needs
- Be timely in development and use
- Maintain sufficient detail to implement regulations
- Sustain active and expert volunteer base
- Ensure adequate feedback from users

CONCLUSION

- ASME and other SDOs have made a significant long-term contribution to the enhancement of nuclear safety
- NRC continues to rely heavily on the use of consensus codes and standards, and the staff continues to participate actively in their development
- Benefits accrued from consensus codes and standards are dependent upon SDOs and users working together to maintain a credible process

Colin B. Church

Consumer Product Safety Commission

BACKGROUND

Saving lives and reducing serious injuries is the business of the U.S. Consumer Product Safety Commission (CPSC). To help do this the Commission has been providing technical support to the development of national consensus voluntary standards since it was established nearly 25 years ago.

The Commission is an independent federal regulatory agency established by Congress in 1973 to protect the public from unreasonable risks associated with consumer products. It was established to reduce the tragic estimated annual losses of 21,400 deaths, 29,400,000 injuries resulting in hospital emergency room visits, and $200 billion in societal costs associated with consumer products.

To help reduce these losses, the Commission has worked with national consensus voluntary standards coordinating/developing groups for over two decades to provide effective, timely safety standards. CPSC staff provide injury information and technical support to 40-50 standards development activities each year. These are handled primarily by ANSI, ASTM, and UL. Not only is it a statutory requirement that the CPC use voluntary standards, subject to certain caveats, it is believed that in so doing the Commission also saves time and money.

In the future, it seems likely the CPSC will continue to utilize non-government safety standards. At the same time the CPPSC staff will seek to improve: (1) the effectiveness and industry use of consumer product voluntary safety standards, (2) openness and balance of interests in the standards development process, and (3) timeliness in the development and implementation of safety standards.

THE PROBLEM

Estimated Annual Losses Associated with Consumer Products

- 21,400 Deaths
- 29,400,000 Injuries
- $200,000,000,000 in Societal Cost
- 15,000 Different Types of Consumer Products

CPSC'S VOLUNTARY STANDARDS EXPERIENCE

- Started in 1973
- Saves Lives; Reduces Serious Injuries
- Saves $ and Time
- Focuses Expertise

1997 OPERATING PLAN
VOLUNTARY STANDARDS UNDER DEVELOPMENT

PARTICIPATION LEVEL

FIRE/GAS CODES & STANDARDS
1. Camping Equipment
2. CO Detectors
3. Gas Water Heaters
4. Unvented Gas Appliances
5. Ranges and Ovens
6. Upholstered Furniture

SPORTS AND RECREATION
7. Bike/Rec. Helmets
8. Soccer Goals

CHILDREN'S PRODUCTS
9. Chairs, Bean Bag
10. Furniture Tipover
11. Playground Equip., Home
12. Playground Equip., Public
13. Playground Equip., Soft
14. Playground Surfacing
15. Window Guards

MECHANICAL CODES & STANDARDS
16. Pools and Spas

MONITORING LEVEL

1. Fireworks Devices

ELEC./POWER CODES & STDS.
2. Christmas Tree/Decor. Lighting
3. Countertop Cooking Appliances
4. Elec. Reinspection
5. Lamps, Portable
6. National Elec. Code
7. Plastic Applications
8. Recharge. Batteries
9. Shock Protection Devices

CHILDREN'S PRODUCTS
10. Activity Centers, Stationary
11. Beds, Toddler
12. Blind Cords
13. High Chairs
14. Cribs
15. Infant Bedding
16. Strings in Clothing
17. Toy Safety
18. Walkers, Baby

FIRE/GAS CODES & STANDARDS
19. Furnaces, Central
20. Furnaces, High Efficiency
21. Gas Systems: Overpressurization
22. LP Gas Code
23. National Fuel Gas Code
24. 20 lb. Systems, Gas
25. Vented Gas Room Heaters

MECHANICAL CODES & STANDARDS
26. Escalators
27. Fun-Karts

CHEMICAL HAZARDS
28. ASHRAE IAQ Standards
29. Child Resistant Packaging
30. Lead Abatement

THE FUTURE

- o Continue to Use Voluntary Standards
- o Work to Improve:
  - . Effectiveness
  - . Use
  - . Openness
  - . Balance
  - . Timeliness

SOLVING THE PROBLEM

- o Effective, Timely National Consensus Safety Standards
- o A Statutory Requirement
- o CPSC Provides Injury Information & Technical Support
- o 46 Activities in FY 1997: ANSI, ASTM & UL

Section 4

Regulatory Standards Panel on Energy and Environment

Introduction to the Partnership In RBCA Implementation (PIRI)

Presented at the

National Institute of Standards & Technology

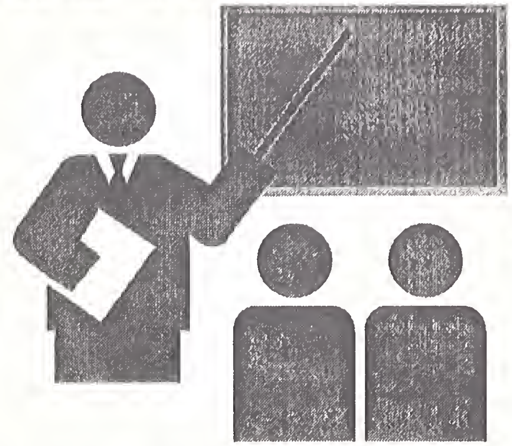
"Using Voluntary Standards in the Federal Government

Conference

Gaithersburg, Maryland

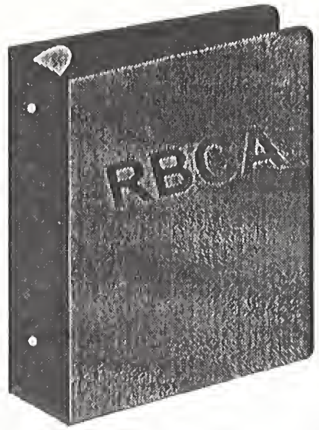
September 8, 1997

Agenda: Overview



- Introductions
- Describe the Rationale behind the Partnership in RBCA Implementation (PIRI)
- Provide an Overview of the PIRI Framework
- Provide an Update on the RBCA Training Initiative
- Additional RBCA Information Sources

Risk-Based Corrective Action (RBCA)



Definition: **A streamlined approach in which exposure and risk assessment practices are integrated with traditional components of the corrective action process to ensure that appropriate and cost-effective remedies are selected, and that limited resources are properly allocated**

Goals:

1) Protection of human health and environment

2) Practical and cost-effective

3) Consistent and technically-defensible

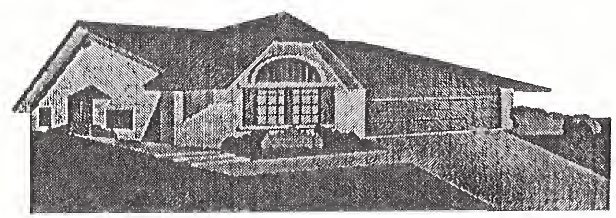
ASTM E 1739: Guide to Risk-Based Corrective Action at Petroleum Sites

- **Outlines framework for integrating traditional clean-up methods with a risk-based decision-making process**
- **Describes steps and philosophy to build the framework**
- **Provides for the integration of State regulatory policies**
- **Provides a technically defensible risk-based process to justify decisions**
- **ASTM provides default toxicity, fate, transport and biodegradation equations, for training purposes**

E 1739 RBCA

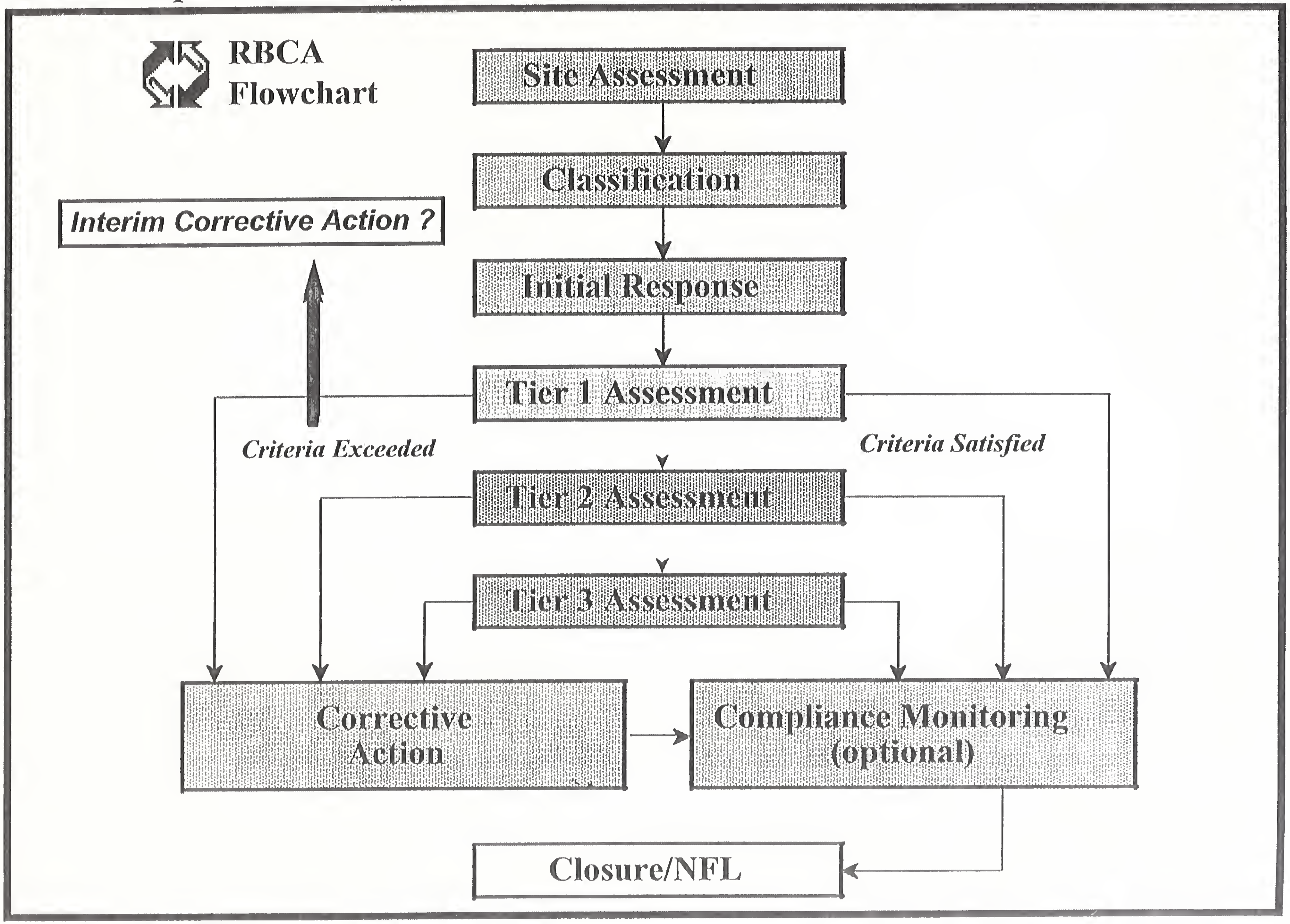
State Policy

Issues



State Specific RBCA Program

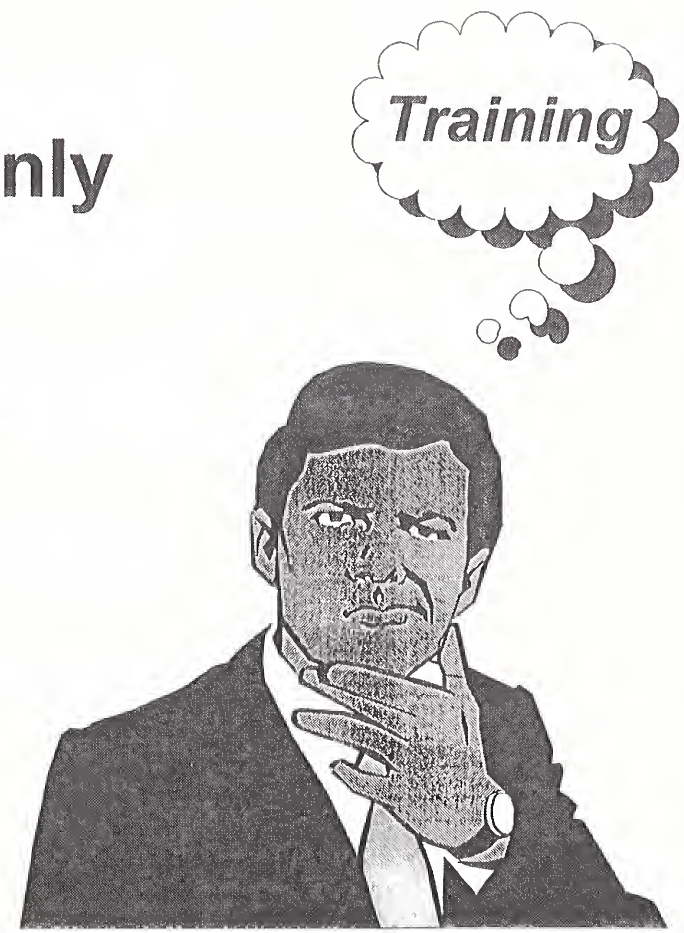
Partnership In RBCA Implementation (PIRI) Overview



Steven D. McNeely, U.S. EPA-OUST

RBCA - Potential Issues

- Misconceptions
- Used as a closure tool only
- Used as a delay tactic
- Lack of qualified people
- Knowledge gaps
- Policy Issues



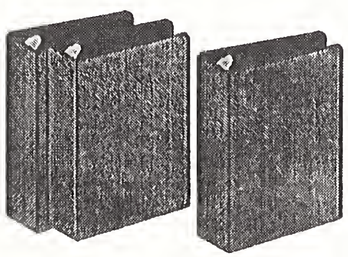
Self Proclaimed RBCA Experts

PIRI Task Group Activities

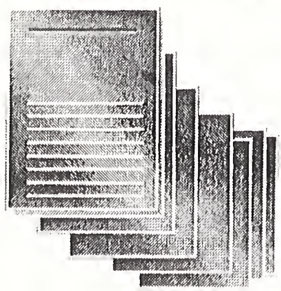
- RBCA Training Program
  - Module 1: Orientation
  - Module 2: Risk Assessment Fundamentals
  - Module 3: Policy Issue Workshop
  - Module 4: State Program Implementation

- RBCA Guidelines and Tools

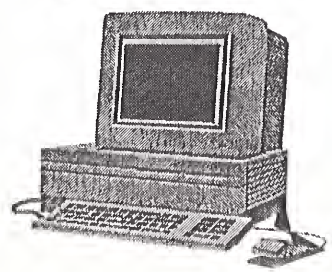
Manuals



Worksheets



Spreadsheet

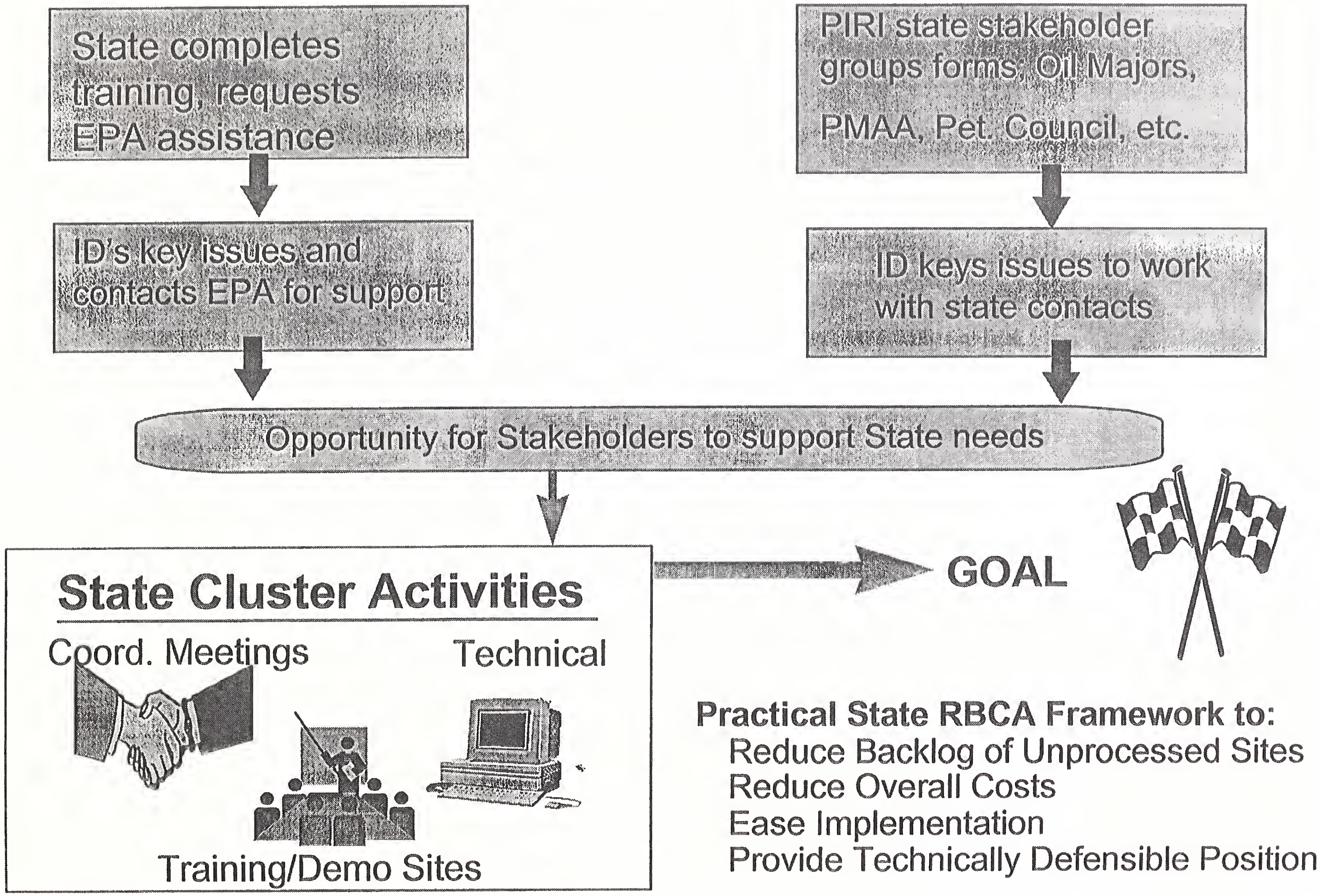


Partnership In RBCA Implementation (PIRI)

VOLUNTARY MEMBERS	ROLE
ASTM	■ RBCA training programs
U.S. EPA	■ Funding and leadership via ASTM Cooperative Agreement
Industry	■ Funding and tech support via MOU.
State Agencies	■ Information exchange, peer support, guidance

Goal: Support training and RBCA program implementation for environmental regulatory agencies nationwide.

Vision of PIRI State Process



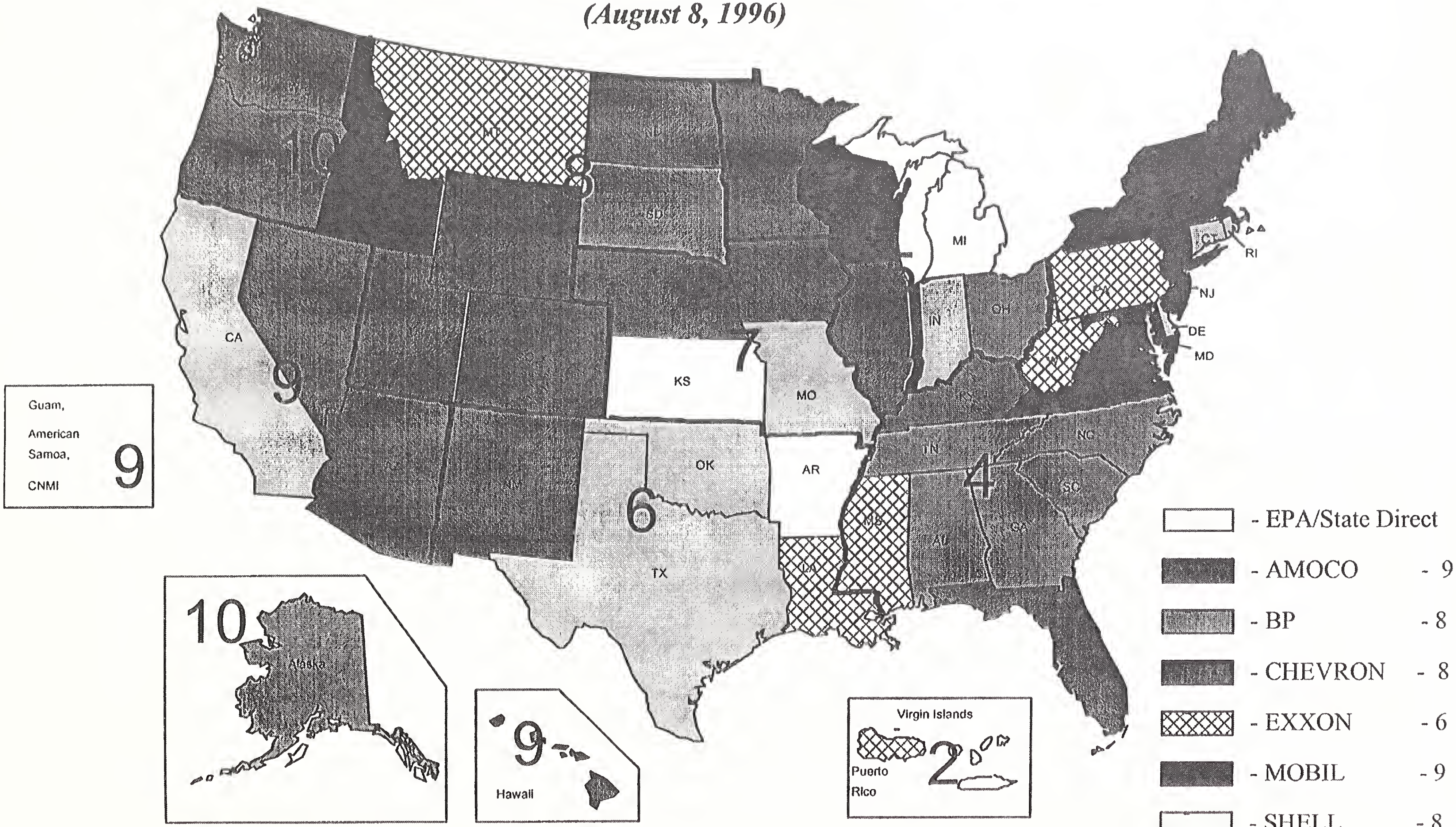
Reasons Behind PIRI's Success

- Coordination with Appropriate Regulators
- Open Communications
- Support the National RBCA Training Initiative
- Technical Assistance
- Support the Testing and Evaluation of Policies

Risk-Based Corrective Action

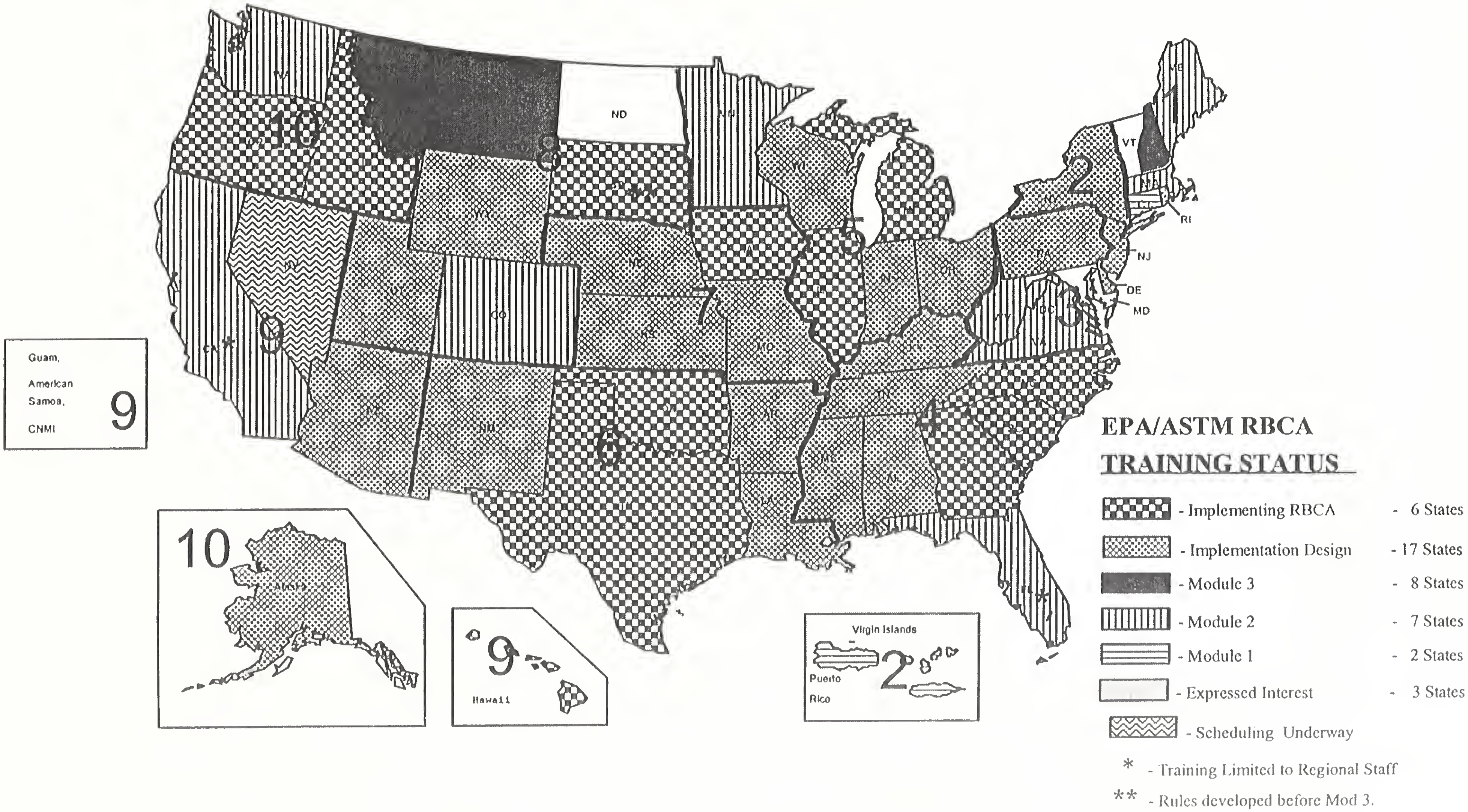
List of Key Stakeholders

(August 8, 1996)

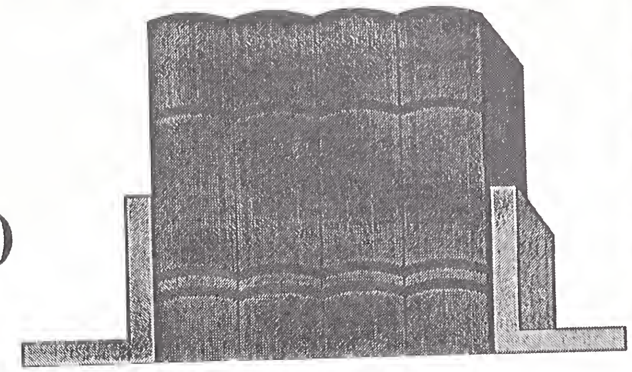


Risk-Based Corrective Action
UST Program Training Status

(September 8,1997)



Resources -



- **USEPA Contacts (e.g., HQ & Regional)**
- **ASTM Task Group Members**
- **ASTM Certified Trainers**
- **USEPA Risk and Exposure Assessment Guidance**
- **Risk Evaluation Software (e.g.,. API DSS, PCGEMS, RISKPRO, etc.)**
- **Fate and Transport Models**
- **Worksheets/Spreadsheets...**
- **TPH Working Group**

For Additional Information Contact:

- CLU-In BBS UST SIG - (301) 589-8366
  - RBCA Talk, Case Studies, Training Info and more
  - OSWER Directive 9610.17 - March 1, 1995
- Office of Underground Storage Tanks (OUST) INTERNET Homepage
  - http://www.epa.gov/OUST
- Your State UST Implementing Agency
  - Status of Risk-Based Decision Making Guidelines

UST Program RBCA Training Summary

49 States/territories have entered the RBCA scheduling/training loop (i.e., either expressed an interest or actually receiving training assistance). The support provided to each state varies according to their understanding of the risk-based concept and compatibility of their rules/regulations to EPA's RBCA approach. The breakout includes:

We are actively working with 49 states/territories

34 States are in the implementation phase (i.e., completed Module 3 and are developing and/or refining administrative practices to foster RBCA's use).

MI, SC, GA, SD, TX, OR, IA, ID, OK, IL, HAWAII, NORTH CAROLINA, Louisiana, Alabama, New York, Utah, Ohio, New Jersey, Indiana, Nebraska, Tennessee, Kentucky, Pennsylvania, Mississippi, Arkansas, Kansas, New Mexico, Arizona, Missouri, Delaware, Wyoming, Rhode Island, Alaska and, Wisconsin****

4 States/territories are scheduled to complete Module 3 soon or previously completed Module 3, and could proceed to the implementation design phase.

Montana, New Hampshire, Puerto Rico and, Virgin Islands.

11 States/territories received Module 1& 2 training but have not continued to Module 3.

Virginia, West Virginia, Minnesota, Massachusetts, Washington, Connecticut, Colorado, Florida*, California*, the District of Columbia & Maine.

1 additional State has expressed interest in obtaining either ASTM RBCA training &/or implementation assistance:

Nevada

LEGEND:

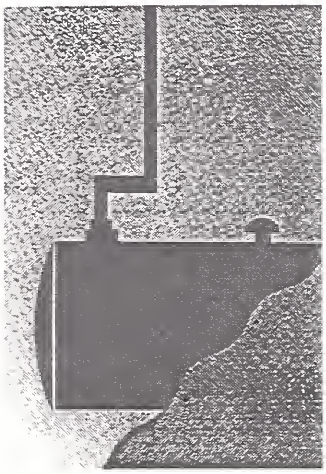
* = A comprehensive RBCA training schedule is being developed for each of the respective District and/or regional water boards (designated implementing agencies).

** = The State skipped Module 3 training and subsequent evaluations (i.e., site demonstrations) to promulgate RBCA guidance documents and/or legislation.

HIGH BOLD = **MI, SC, GA, SD, TX, OR, IA, ID, OK and IL** have completed all aspects of the EPA-ASTM RBCA training, issued guidance manuals, and are implementing a RBCA process customized for use in their state.

BOLD UPPERCASE = The state developed and issued their RBCA process prior to or in lieu of obtaining comprehensive EPA ASTM RBCA Training. Technical - implementation assistance may be provided in lieu of the comprehensive RBCA training.

NOTE: The information provided in this graphic/narrative does not provide an accurate summary of the use of risk-based decision making (**RBDM**) in all states. This summary **PRIMARILY** provides information on the status of ASTM RBCA training in the UST program. Numerous States have established RBDM programs other than ASTM's RBCA.



PIRI Issue Papers

EPA Number 510-R-97-001

A collection of technical issue papers written by EPA, state, and industry members of the Partnership In RBCA Implementation

What are the "PIRI" papers?

The Partnership In RBCA Implementation (PIRI) is a collaboration of industry, states, EPA and ASTM. The partnership was established to encourage and support state efforts to implement a risk-based approach to corrective action at federally regulated UST sites involving releases of petroleum or petroleum products. In a series of papers they have authored, individual PIRI members discuss issues involved in implementing RBCA and present options for overcoming obstacles.

What issues are covered?

The papers discuss RBCA issues associated with natural attenuation; the definition of "contaminant;" "No Further Action" letters; selection of carcinogenic target risk levels for soil and groundwater remediation; off-site movement of chemicals of concern; institutional controls; groundwater nondegradation policies; and using TPH. All papers represent only the views of their authors; they do not reflect official EPA policy or the positions of PIRI member organizations.

How can I get a copy?

EPA has posted the ***PIRI Issue Papers*** on the Office of Underground Storage Tanks World Wide Web site at **http://www.epa.gov/OUST/rbdm/piriacts.htm**. You are free to read the papers on-line, or download them. If you do not have Internet access, you may order a copy of the ***Papers*** by calling the National Center for Environmental Publications and Information (NCEPI) toll-free at 1-800-490-9198.

Tentative List of Key Stakeholders (pending approval by States)					
Shell:	<u>Connecticut</u> <u>California</u> <u>Rhode Island</u> Texas Indiana Missouri Delaware Oklahoma	<u>Total:</u> 8 States	**EPA:**	<u>Michigan</u> Kansas Arkansas	<u>Total:</u> 3 States
Amoco:	<u>Iowa</u> <u>Illinois</u> <u>New Jersey</u> <u>Minnesota</u> Colorado Nebraska Wyoming Florida Utah	<u>Total</u>: 9 States			
Mobil:	<u>New York</u> <u>Idaho</u> Wisconsin Virginia Massachusetts Maryland Maine Vermont New Hampshire	<u>Total:</u> 9 States			
Exxon:	Louisiana Montana Pennsylvania West Virginia Washington, DC Mississippi Puerto Rico	<u>Total:</u> 6 States & PR			
BP:	<u>South Carolina</u> <u>Ohio</u> <u>Georgia</u> <u>Alaska</u> <u>Tennessee</u> <u>North Carolina</u> South Dakota Alabama	<u>Total:</u> 8 States			
Chevron:	<u>Kentucky</u> Washington Arizona Nevada North Dakota New Mexico Oregon Hawaii	<u>Total:</u> 8 States			

Underlined States represent States where company is already acting as "Sponsor".

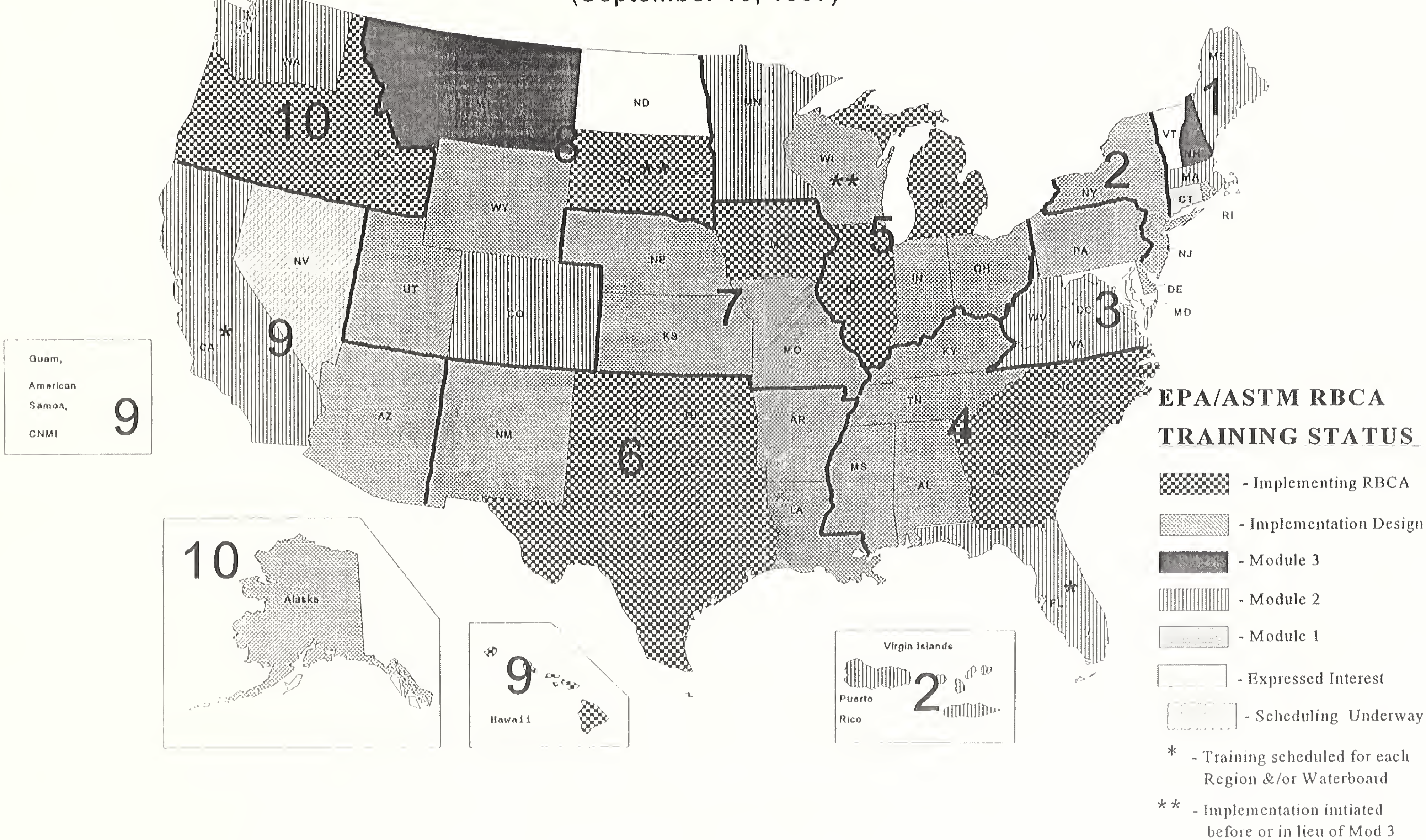
PIRI Key Stakeholder Contacts

NOTE: Contact your EPA Regional RBCA Contact to get in touch with your PIRI Key Stakeholder

Amoco Corporation:	Geoffrey Gilman
Shell Oil Company:	Wayne Hamilton
Chevron Products Company:	Jeff Hartwig
Mobil Oil Corporation:	Mark W. Malander
British Petroleum:	Jim Rocco Lesley Hay Wilson
Exxon:	Len M. Racioppi

Risk-Based Corrective Action
UST Program Training Status

(September 10, 1997)



NOTE: The information provided in this graphic/narrative does not provide an accurate summary of the use of risk-based decision making (**RBDM**) in all states. This summary **PRIMARILY** provides information on the status of ASTM RBCA training in the UST program. Numerous States have established RBDM programs other than ASTM's RBCA.

USING VOLUNTARY STANDARDS IN THE FEDERAL GOVERNMENT

DR. CAROLINE PURDY

DEPARTMENT OF ENERGY

OFFICE OF ENVIRONMENTAL MANAGEMENT

NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY

GAITHERSBURG, MD - SEPTEMBER 8, 1997

Lessons Learned from ITRC/ASTM Partnership

Science & Technology

- Partnership provided appreciation from both sides perspective of how standards are used in environmental activities
- Acknowledgment of different levels of states acceptance of standards:
  - awareness of good standards - "use as needed"
  - formal acceptance - new guidance policy
  - standard could evolve into a regulation
- From DOE perspective: ability to introduce and gain acceptance of ESC approach by regulators should be smoother

But only time will tell whether ESC becomes common practice!

ITRC Impact on ASTM - ESC Guide

- *review resulted in better, more user-friendly standard*
- *highlights benefits of meaningful stakeholder participation*
- *clarifies minimum ASTM criteria for determining whether a site characterization project qualifies as ESC*
- *revisions include need for all relevant contaminant migration pathways addressed*
- *encourages active, regulatory input*
- *agree with dynamic work plan approach*

Results from ITRC/ASTM Partnership on ESC Guide

- *overall, ESC Guide favorably received by ITRC*
- *reviewed by 30 ITRC members (including states and stakeholders)*
- *expected to be used by states as tool in "toolbox" of environmental characterization techniques*
- *states open to use of ESC, without specific commitment*
- *from DOE perspective: provided the forum for ESC information to be disseminated*

ITRC/ASTM Partnership Formed in September 1996

ITRC:

- *agreed to pilot the development of the ASTM - ESC Guide as a process to use for building a common guidance for states for acceptance of new environmental technologies and/or processes*
- *27 states reviewed extensively the ASTM - ESC Guide providing valuable input*

Caution:

- *States will not give up their prerogative of regulating environmental activities*
- *Confusion between ASTM Standard/Guide and regulation*

Interstate Technology and Regulatory Cooperation (ITRC)

Participants:

- *State-led initiative with 27 states*
- *Federal partners include: Dept. of Energy, Dept. of Defense, Environmental Protection Agency*
- *Public stakeholders*

Goal:
Cooperate on an interstate basis to expedite the review, approval & deployment of innovative clean-up technologies, guidances, and protocols

Underlying Barrier to ESC Acceptance

- *Regulatory acceptance of new environmental technologies, processes, or methods*
- *States authority*
- *Reluctance of venture capital investment in environmental technologies due to lack of ability to create market size*
- *No model to get innovative technologies accepted in multiple states*

ASTM Initiative

Based on general lack of progress toward adoption of ESC approach

- *Initiated development of ASTM standard to build a broad-based consensus for ESC*
- *In April 1996, established ASTM - ESC Task Group*
- *Several revisions based on member input*
- *Vote taken in Nov. 1996 resulting in Provisional Standard status (subcommittee level)*
- *2 yr trial period with many additional revisions*
- *Final vote on full standard status expected in January, 1998 (full committee)*

Lack of Adoption of ESC Continued at DOE Sites

- By 1996, ESC still not accepted by DOE remediation contractors for site characterization activities
- Program managers cautious - reluctant to change conventional methods
- Lack of exposure/knowledge of the novel approach
- Lack of confidence by cleanup staff toward R&D generated suggestions

ESC Approach Implemented at Several DOE Sites

- Several demonstrations at DOE sites
- Documented cost and schedule savings at:
  - Pantex Plant, Amarillo, TX
  - Savannah River Site, Aiken, SC
- Documented acceptance and endorsement by regulators
- Documented a more accurate characterization of site contamination problem

Expedited Site Characterization (ESC) Approach Developed - 1992

A methodology developed to overcome the limitations of conventional approach

Key Elements:

- *understand geology and hydrogeology of the migration pathways before tracking contaminant plumes*
- *integrated, multidisciplinary team of experienced professionals*
- *1-2 field mobilizations for all technologies*
- *multiple, cost effective, non- and minimally invasive technologies*
- *daily data analysis, integration, and validation in the field*
- *flexible, dynamic work plan with on-site decision making*
- *few monitoring wells*
- *effective communications with regulators*

Characterization, Monitoring, and Sensor Technology (CMST) Program

CMST program was charged to develop and test innovative or emerging characterization technologies

- *Field sampling and analytical methods*
- *Real-time sensors deployed in the subsurface*
- *Geophysical methods to "image" the subsurface*
- *Improved ground water flow detection methods/techniques*
- *Data fusion and data visualization techniques*

Impact: Became evident individual tested technologies alone was not going to have a major impact on cost/schedule of characterization activities

Need: New approach/process for Phase I/Phase II characterization activities

Situation Analysis - 1990 - 1993

Problem - environmental site characterization activities were costly, time consuming, inefficient, and often inaccurate

- *$2-3 B annually spent on characterization activities*
- *phase I and phase II conventional characterization process was very ineffective*
- *relied on essentially only intrusive methods and very formal field plans*
- *regulatory driven decision making*

Introduction

- *Dept. Of Energy, Office of Environmental Management, Office of Science and Technology*
- *Mission: To clean-up the legacy waste from weapons production activities from the last 50 years*
- *Environmental activities (regulations/ enforcement) fall under states purview*
- *Regulatory driven activities*

DOE Case Study: ASTM Standard Developed

"DOE initiates the development of an ASTM Standard for a novel site characterization approach for environmental activities"

- ***Why?***
- ***Who was involved?***
- ***What did they do?***
- ***What is the status today?***
- ***What is the impact?***

Section 5

Procurement Standards Panel

Voluntary Consensus Standards Initiatives

Presented by
James D. Nicolo, DISC
Sept. 8, 1997

Topics

★ Background

★ Statistics

★ Accomplishments

★ Process

★ Initiatives

Background

- ★ DoD Policy
  - – Eliminate MILSPECS
- ★ DISC Fasteners Experience
  - – Parts Procurer/Supplier
  - – Govt/Industry Engineering Interface
- ★ Current Role as PA
  - – Opportunity for Improvement
  - – Eliminate or Fix

Statistics

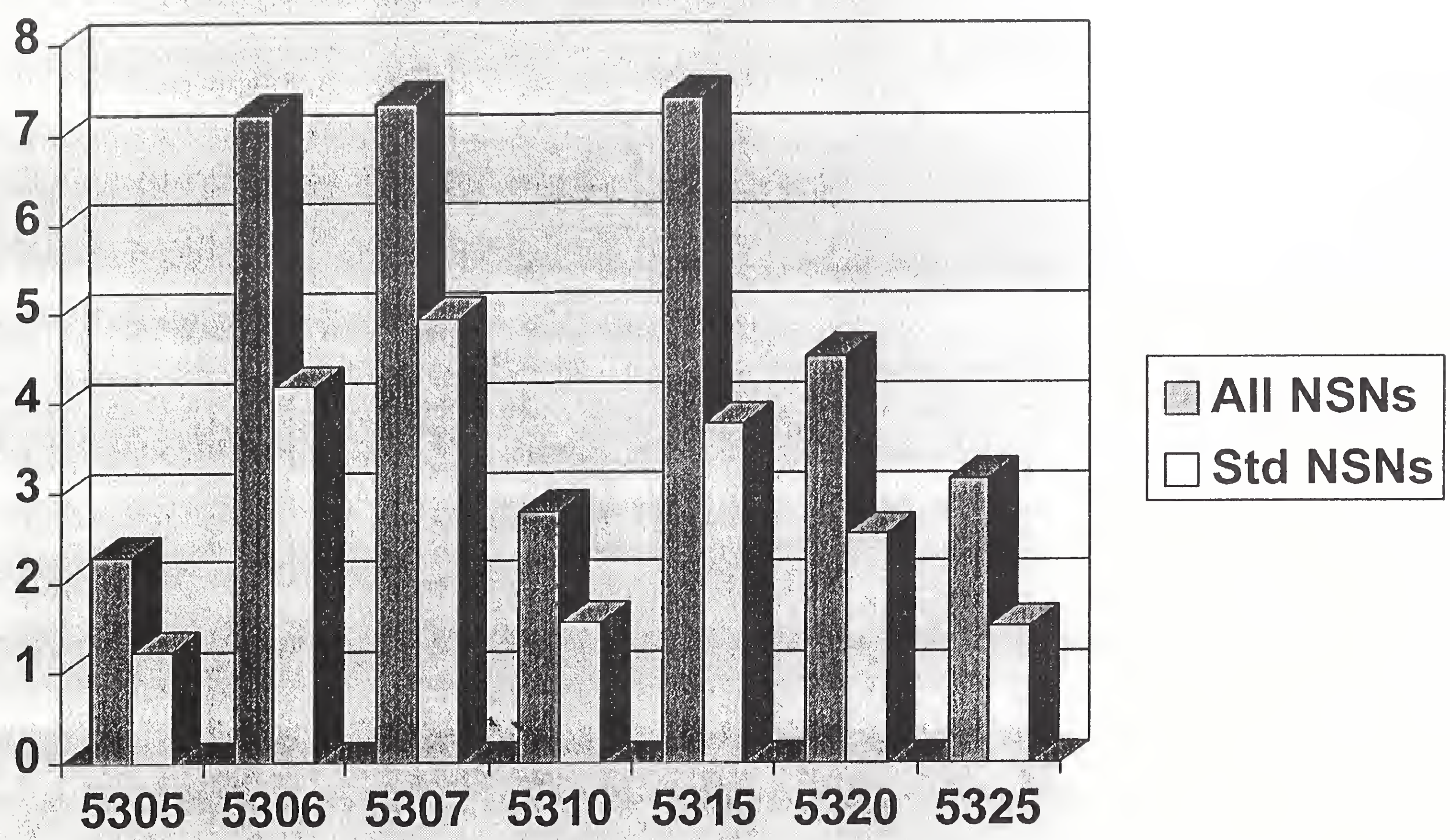
- Current PA for 5,667 Docs
  - 1,628 NGSs
  - 134 CIDs
  - 2,167 Govt Docs
  - 1,738 Canc/Inac Docs
- NGS Bodies
  - NASC, ASTM, SAE, ANSI, ASME
- 28 Committees
  - 31 Participants

Statistics (cont'd)

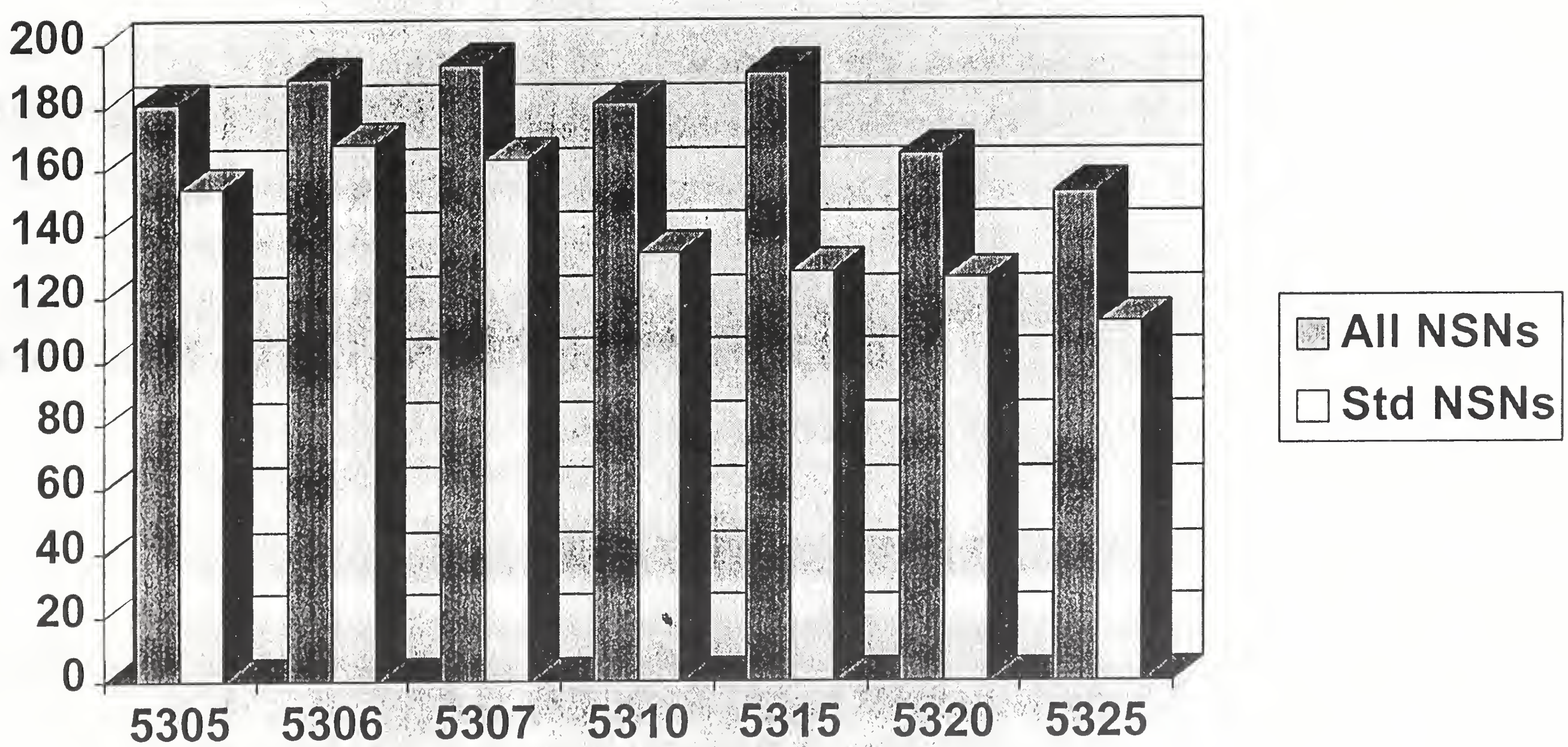
★ DISC's Fasteners Business Profile

- 600K NSNs Managed
- 100K Contracts Placed
- $370M Sales
- $250M Obligated

Fasteners
Unit Price Comparison



Fasteners PLT Comparison



Accomplishments
(since Spec Reform)

- ★ 506 NGSs Adopted
- ★ 29 CIDs Developed
- ★ 865 MILSPECs Cancelled/Inactivated
- ★ 485 MILSPECs Updated
  - Revisions/Amendments

Process

★ Determination of Need
- Items Impacted
- Industry Perspective

★ Spec Analysis Meetings
- Consensus Approach
- Accuracy of Reqmts
- Currency of Technology
- Customer Viewpoint

Process (cont'd)

- ★ Committee Participation
  - – Consensus Approach
- ★ Timely Development
  - – Electronic System

Initiatives

- ★ Govt-Ind Fastener Working Gp
  - – OEMs/Mfrs/Labs/Distr/Mil Svcs
- ★ Spec Analysis Meetings

Initiatives (cont'd)

- ★ NASC Project
  - Configuration Control
  - Reconfigure MIL to NGS
  - MS XXXXX to NASM XXXXX
  - DISC - Government Focal Point
- ★ Transition Status
  - 382 Candidates Selected
  - 138 Projects Initiated
- ★ Planned Initiative Completion - Mar 98

CASE STUDY

TRANSITION OF MILITARY STANDARDS AND SPECIFICATIONS TO NON-GOVERNMENT STANDARDS BODIES

Specifications and Standards Reform is a DoD mandated initiative under the umbrella of Acquisition Reform. In the past, Military Service Document Preparing Activities (PA's) were responsible for the development, maintenance, and update of specifications and standards that govern the products that the DoD procures. These specifications and standards are important to the Defense Industrial Supply Center's mission to supply hardware to the military services and various federal agencies. They describe and control the technical characteristics of the products that we buy for our customers. Therefore, they provide the essential ingredients to ensure our procurement and supply of quality, conforming products. Industry too, has a vested interest in these documents. These standards and specifications describe hardware that is not military or government unique, but has widespread use and acceptance in various sectors of industry. In fact, in the aerospace community, both Original Equipment Manufacturers (OEM's) and hardware manufacturers have, over the years, been an integral part of the standards development process. As a consequence of the types of standards we are dealing with, as well as the active participation of various facets of the hardware manufacturing and using community, many hundreds of military documents are *de facto* national, and international standards.

The formidable task of maintaining specifications and standards is balanced against a DoD policy which advocates the elimination, where possible, of military specifications and standards. That policy encourages the development of commercial standards, the adoption and use of Non-Government Standards (NGS's), the replacement of current military documents with ones that are performance-based, or the outright cancellation or inactivation of the military version. To adhere to DoD policy, on the one hand, and to make certain, on the other, that our commodities continue to be adequately and accurately covered by standardization documents, we have developed a plan for the transition of military specifications and standards to NGS's. In pursuing this effort, we are preserving the Part Identification Numbers associated with the military documents that, for both government and industry, are so vital to the logistics support of weapons systems and equipment. Retaining existing part numbers will preserve configuration control on hundreds of thousands of technical drawings, documents, and engineering data. We continue to work closely with the appropriate NGS organizations, the government and industry communities involved in systems design, parts manufacturing and supply, maintenance, use, and testing fields to ensure a viable approach to the conversion of military documents. As a result, we have embarked on a comprehensive program effort with the Aerospace Industries Association, through it's National Aerospace Standards Committee (NASC), and the Society of Automotive Engineers (SAE) E-25 committee on General Standards for Aerospace Propulsion Systems, to transition needed military documents to counterpart Non-Government Standards.

Aerospace Industries Association of America, Inc.

http://www.aia-aerospace.org

EARLY WARNING PROJECT GROUP

GOAL: Maintain Standardization in Aerospace Parts, Materials, and Processes as MIL-SPECs are canceled

USE OF STANDARDS IN TYPICAL AEROSPACE PRODUCTS

		Number of Different Specifications & Standards*	%	Estimated Total Number of Applications	%
Tactical Fighter 	DoD	1,100	55	48,000	32
	NAS	200	10	36,000	25
	SAE	50	2.5	100	
	ASTM	10	0.5	15	
	Non Standards	600	30	62,000	42
		1,960		146,115	
Wide Body Airliner 	DoD	419	20	10,000	6.4
	NAS	122	6	50,000	32
	SAE	86	4	320	2
	ASTM	120	6	1,000	0.6
	Miscellaneous Stds	376	18	9,500	6
	Non Standards	956	46	85,000	53
		2,079		155,820	

What is the Problem?

- Numerous MIL-SPECs define *de facto* international commercial practice (5000 used in aerospace).

- Documents are being canceled in greater volume and more quickly than before.

- DoD Preparing Activities who are not familiar with AIA and needs of aerospace manufacturers now control documents.

- We need greater awareness and coordination.

AIA EWPG Approaches

1. Provide "Early Warning" of MIL-SPEC cancellations through monitoring DoD Databases and Internet Home Pages, as well as expanding communication with Preparing Activities.

2. Work with appropriate Standards Developing Organization to prepare a replacement, if not already available, <u>leveraging</u> committee participation.

3. Publish AIA National Aerospace Standards as appropriate, using "NASM" designation to retain existing part numbers while clearly indicating document source.

4. Provide desired cancellation notice supersession wording to DoD.

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Producing a standard for product data exchange

Presented by Howard M. Bloom, NIST

"Using Voluntary Standards in Federal Government"

September 8, 1997
Gaithersburg, MD

NIST

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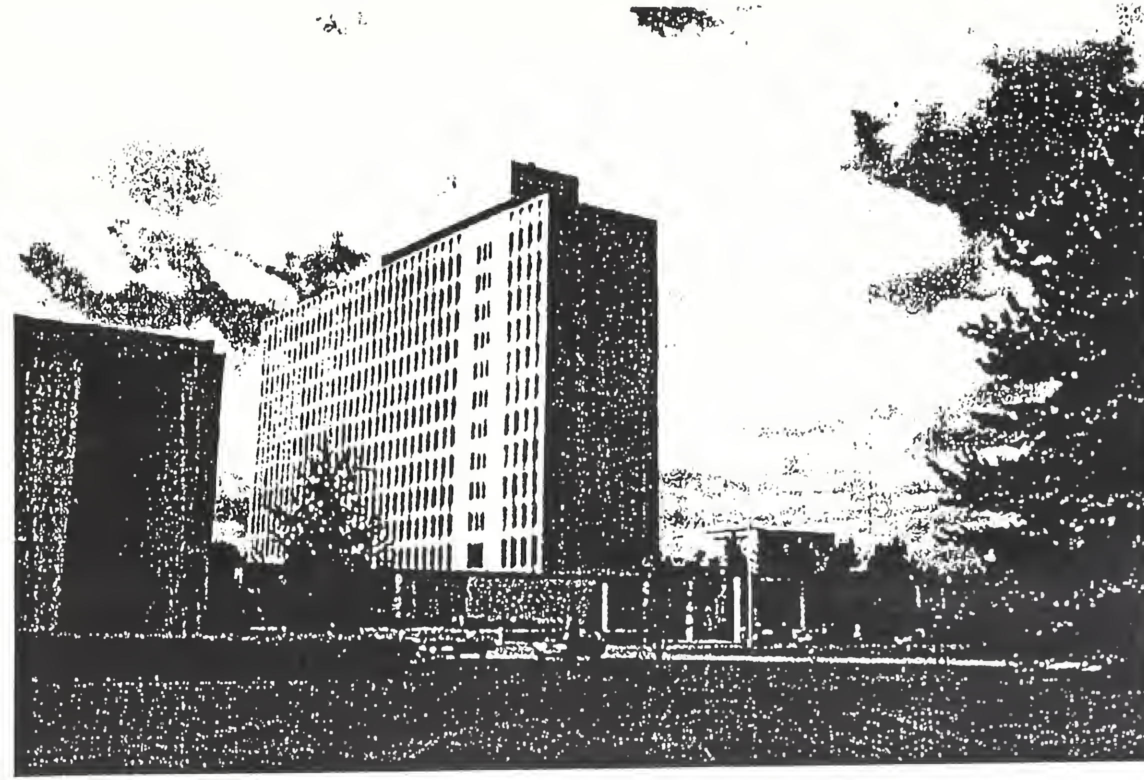
National Institute of Standards and Technology

NIST's primary mission is to promote economic growth by working with industry to develop and apply technology, measurements, and standards.



NIST carries out its mission through a portfolio of four programs:

MEASUREMENTS AND STANDARDS PROGRAM	ADVANCED TECHNOLOGY PROGRAM	MANUFACTURING EXTENSION PARTNERSHIP PROGRAM	NATIONAL QUALITY PROGRAM

NIST

Technical Goals of the Measurements and Standards Program

Laboratory Research and Development

- Perform research in cooperation with industry that anticipates and addresses the most important measurement and standards needs in a timely fashion

National Measurement and Standards System

- Strengthen the national system of standards, measurements, measurement traceability, and conformity assurance

International Measurement and Standards System

- Provide leadership in harmonizing international measurements and standards to facility trade

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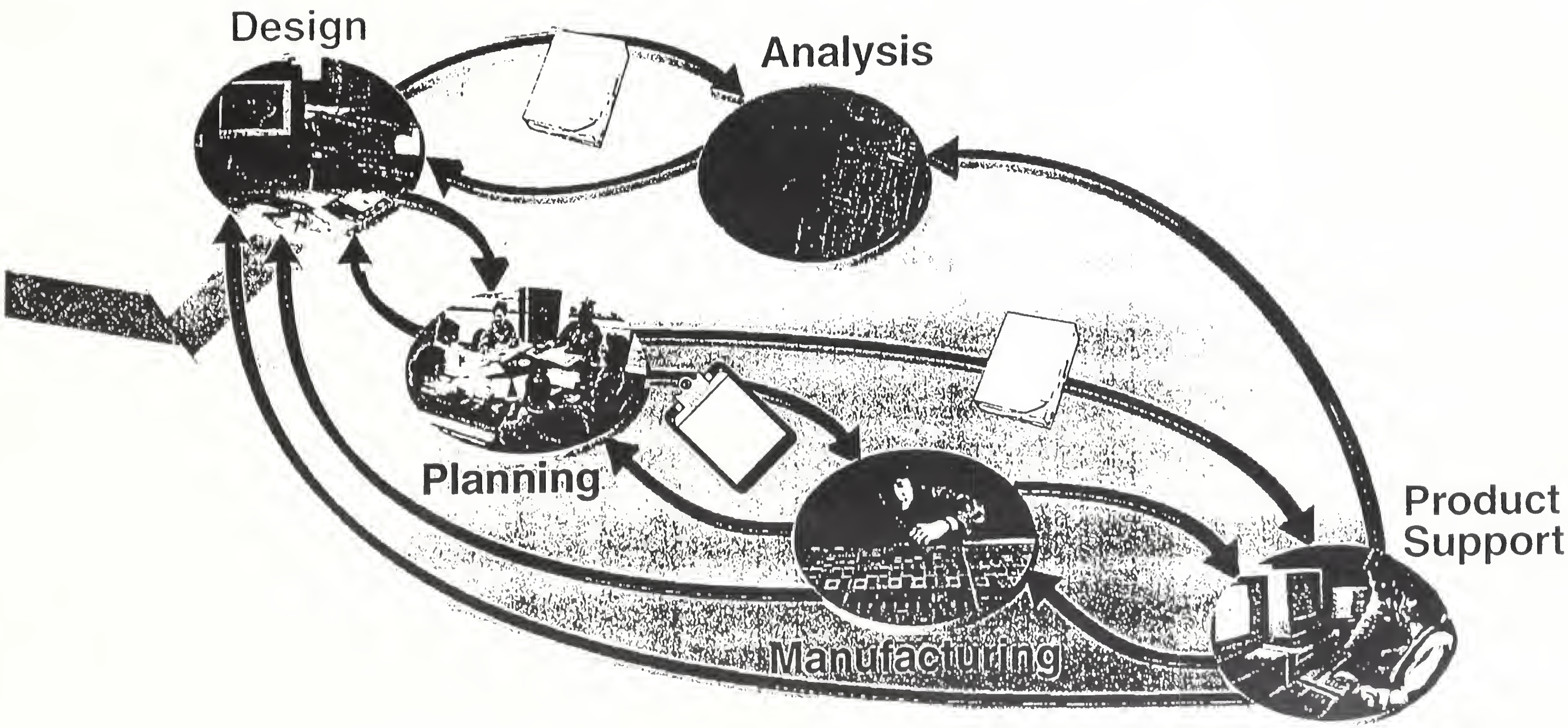
MANUFACTURING ENGINEERING LABORATORY

The Environment for Product Data Exchange



Product Data communication occurs as formal and informal exchanges of spoken and written (documented on paper) information between functional components & enterprises.

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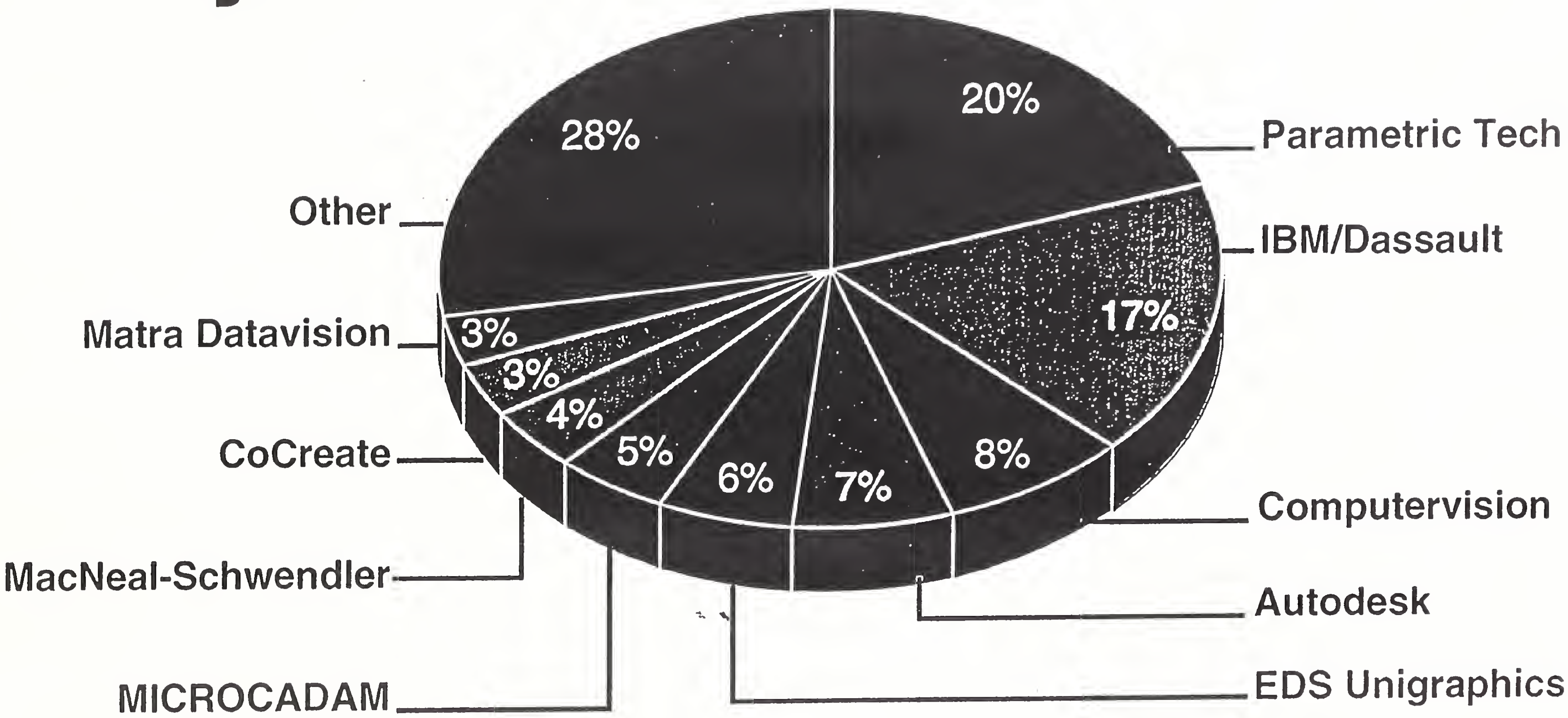
Use by Mechanical Design Systems

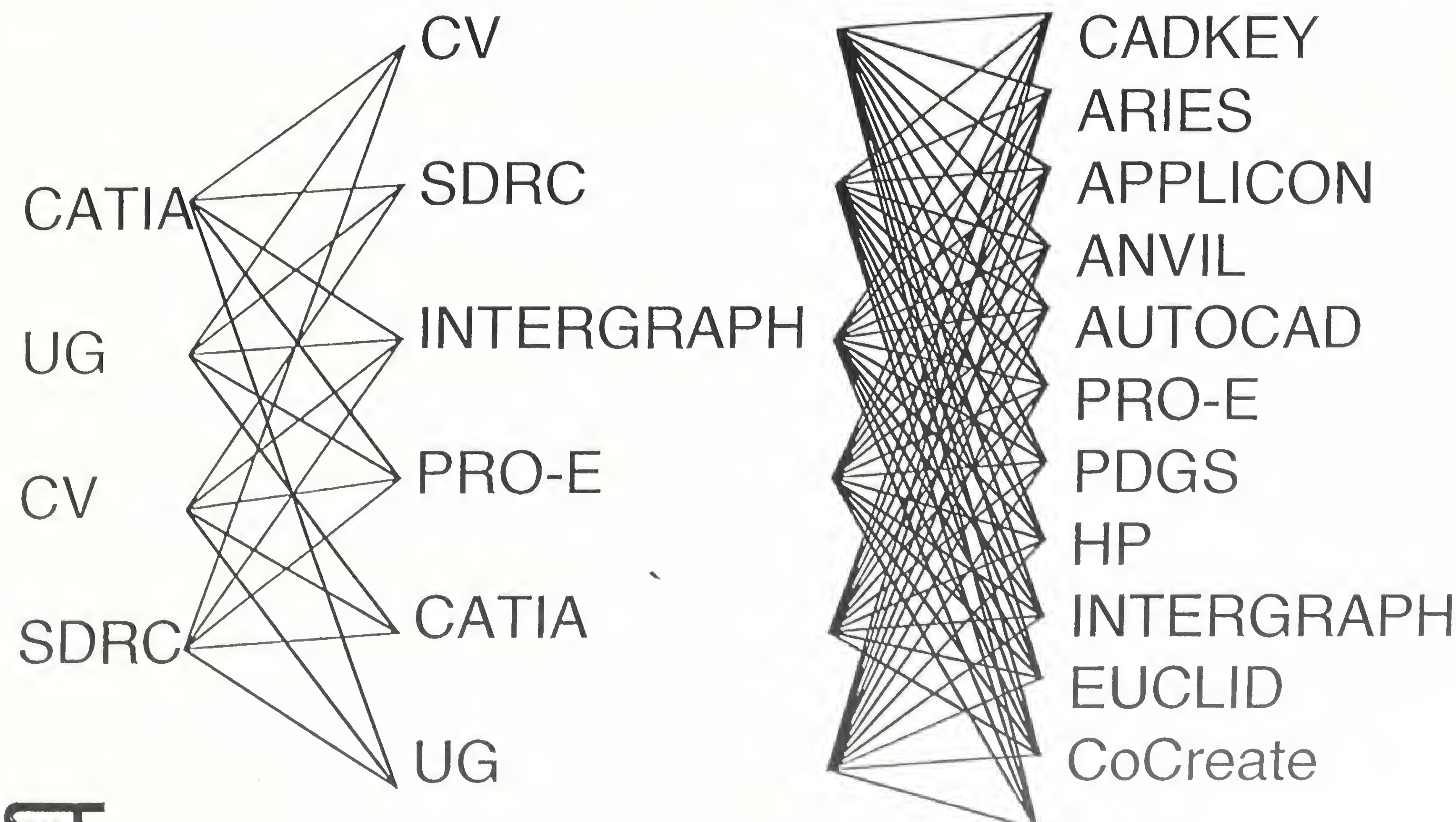


Source: DATATECH

NIST

Without Standards

OEMs | First Tier Suppliers | Sub-tier Suppliers



U.S. Industry Commitment to International Standards

Rationale

- Non-harmonized standards can lead to technical barriers to trade
- Global enterprises must share product data effectively

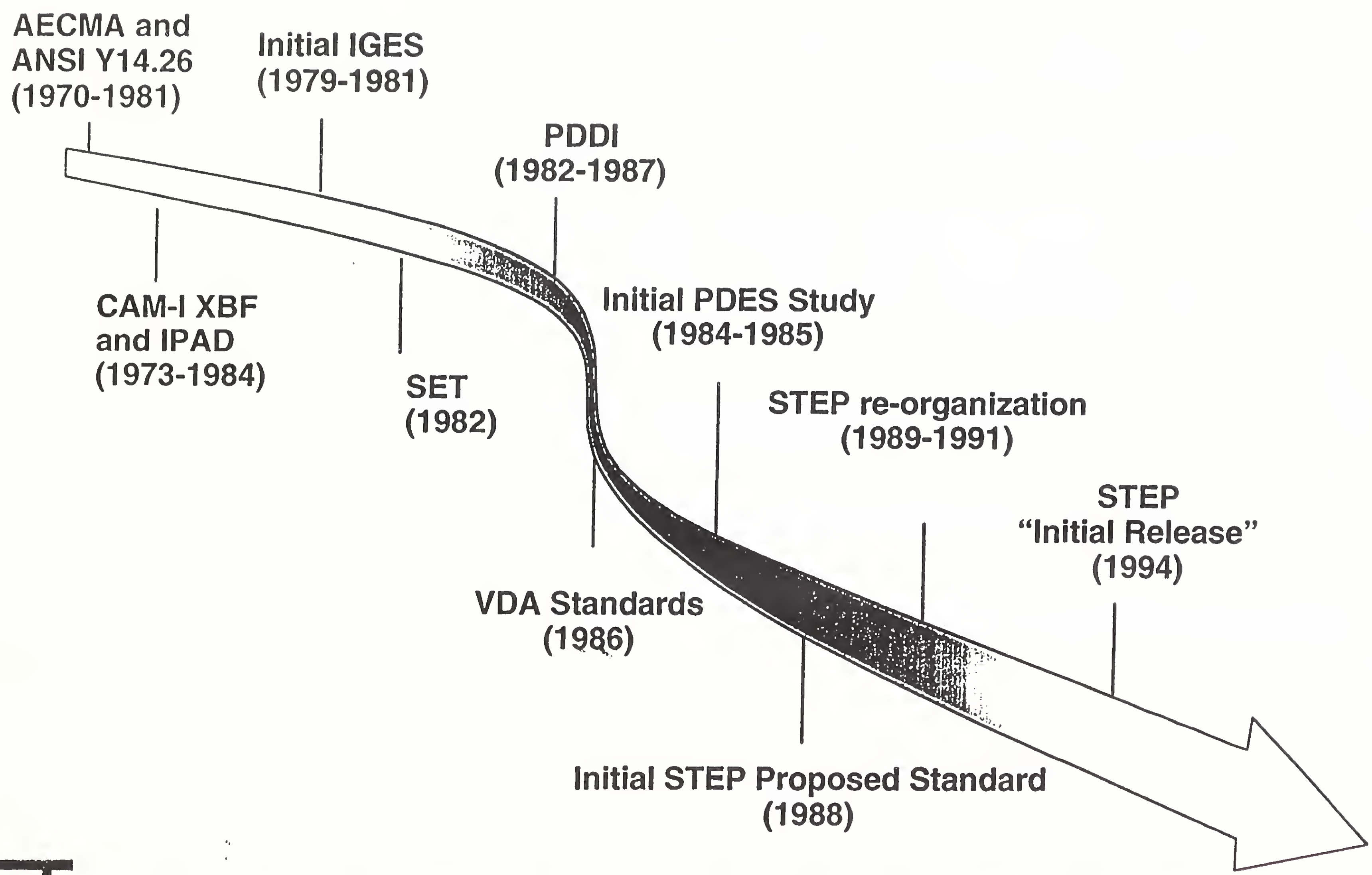
Example: Japanese Industrial Standards Committee Standardized Plan

Japan should participate more actively in international standardization activities

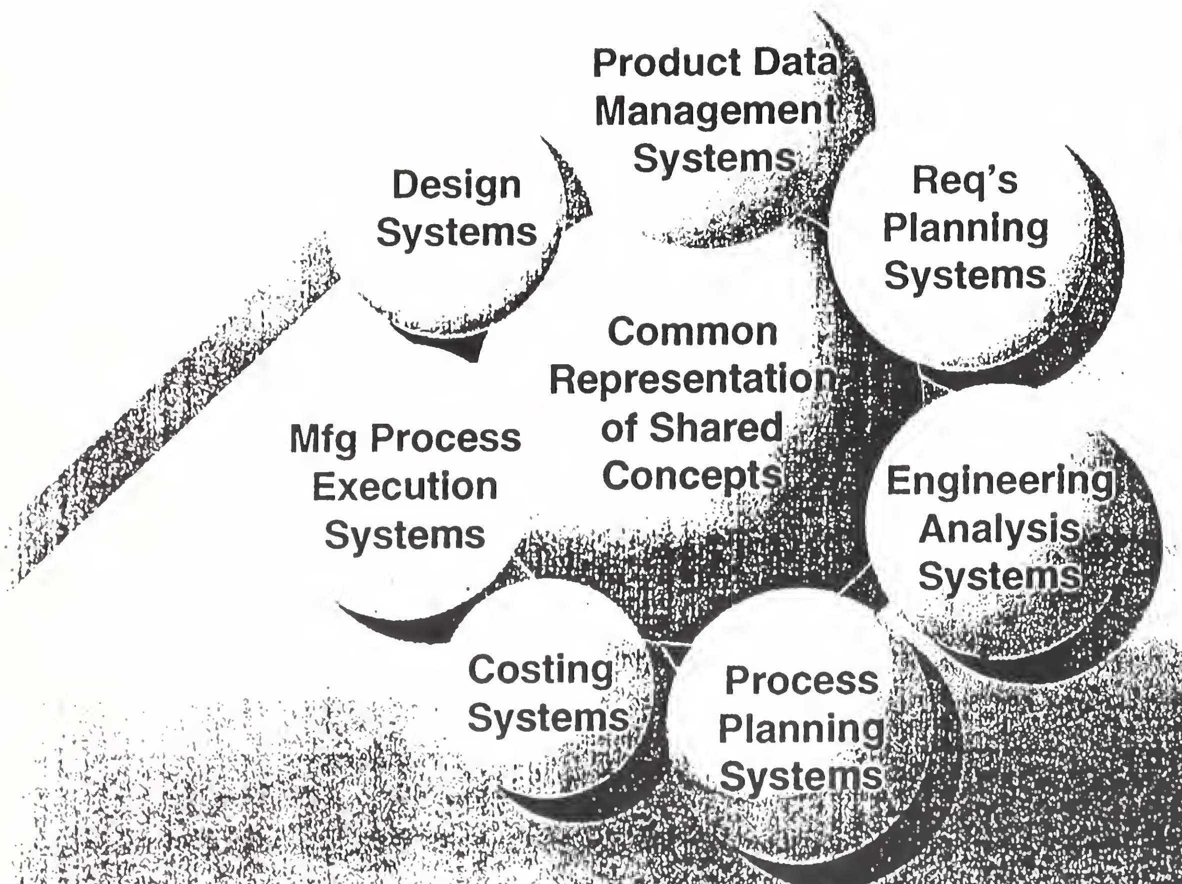
JIS standards should be harmonized more with international standards

Japan should promote international collaboration associated with standardization

Historical Overview



Requirements for an Industrial Data Exchange Standard



Access to All Types of Data Across the Life Cycle

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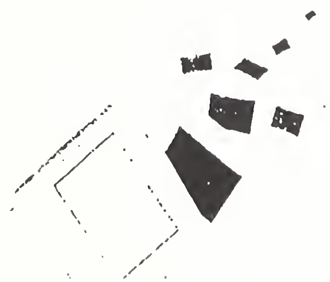
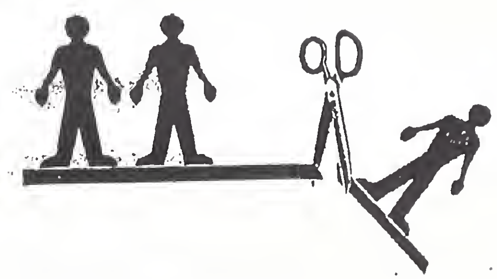
MANUFACTURING ENGINEERING LABORATORY

STEP's Role and Impact

International standard to enable more efficient and effective communication of product data:



Different software applications and hardware



Different organizations involved in the product life cycle

Physically dispersed sites

NIST

Major Organizations

- United States
  - US PRO Data Assoc. (ANSI IGES/PDES Organization)
  - PDES, Inc
  - GM Translation Center
- International
  - ISO TC184/SC4 (Industrial Data - STEP)
  - Japanese STEP Promotion Center
  - ProSTEP (German automotive industry)
  - Australian STEP Resource Center
- NIST (Secretariat for TC184/SC4, IPO support, STEP Testing Service)

STEP Application Protocol

The Application Protocol (AP) utilizes information of integrated resources to represent a particular model of an engineering or technical application

- International Standard (3)
- Draft International Standard (5)
- Committee Draft (11)
- Working Draft (6)
- New Work Item (1)
- Planning (3)

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APs Across Industry Sectors

Configuration Controlled 3D Design of Mechanical Parts and Assembly (203)

PCA and PCB Design Information (210)

Core Data for Automotive Mechanical Design Processes (214)

Ship Structures (218)

Mechanical Product Definition of Process Planning using Machining Features (224)

Building Elements Using Explicit Shape Representation (225)

Plant Spatial Configuration (227)

NIST

Vendor Implementation Claims Furnished by AIAG

	203 3D	202 Drawing	214 Auto. Design
Autocad	Y		F
CATIA	Y	Y	Y
CADDS-5	Y		Y
Pro/Engineer	Y	Y	Y
IDEAS	Y		Y
Unigraphics	Y	F	Y

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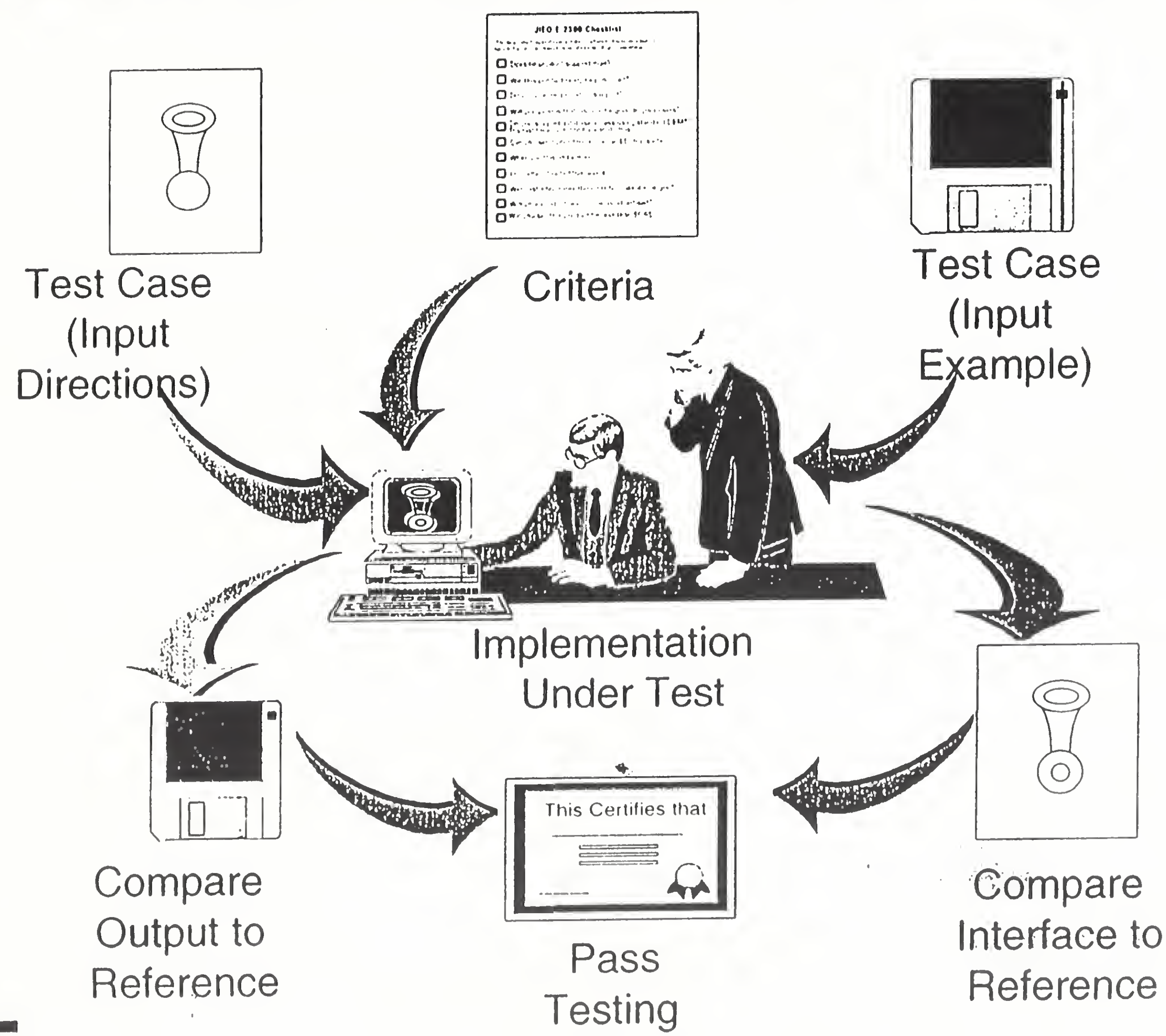
Conformance Testing



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Savings for Vendors Through Conformance Testing

Based on testing done through STEPnet and PDMnet

- Average savings of $637K per CAD vendor based on their $700 estimated cost of isolating error
- Initial seven vendors resolved almost all conformance issues on solid exchange (AP203) in less than one year (3 times faster)

Corporate & Government RFP's
Referencing Product Data Exchange Standards

Sterling Software
COTS products using IGES (including NASA-IGES subset), and PDES/STEP (AP 203)

Centers for Disease Control and Prevention (CDC)
Engineering input formats using IGES

The Coastal Systems Station, Dahlgren Division, NSWC, Panama City, FL
Drawings using IGES

Naval Sea Systems Command
Machine shop services using IGES and STEP

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Savings for Users
(Enabled by Reliable CAD Data Translation)

Eliminates Cost of Multiple CAD Systems

- Up to $200M/year is spent by the suppliers to one US automotive OEM to maintain the different CAD systems. Other costs exist: CAD seat, training/proficiency, underutilized equipment, ...

Reduces Time/Expense of CAD Data Translation

- US study estimated that 25% of the cost of automotive tooling is from data translation
- German study put cost of design data exchange/translation at $25.00 per vehicle. ($350M min/year for US auto industry)

Provides Way for Small Suppliers to Participate

- Typical CAD proprietary translator costs are out of the range of small firms. So they rely on inadequate data exchange formats (IGES or DXF), service bureaus , or paper drawings/re-entry

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Commitments by Industry to use STEP

Auto

Audi
AUDI AG
GM General Motors
BMW
BMW AG
Mercedes-Benz
OPEL
CHRYSLER CORPORATION
FIAT

Plant

BECHTEL
BLACK & VEATCH
Pritchard
DUPONT
MERCK
The Shaw Group Inc.
dassault systemes of America
INTERGRAPH
JOHN BROWN
COMPUTERVISION

Aerospace

LOCKHEED MARTIN
Lucas
PRATT & WHITNEY DEPENDABLE ENGINES
BOEING
snecma
ROLLS ROYCE
AEROSPACE GROUP
Allison Engine Company

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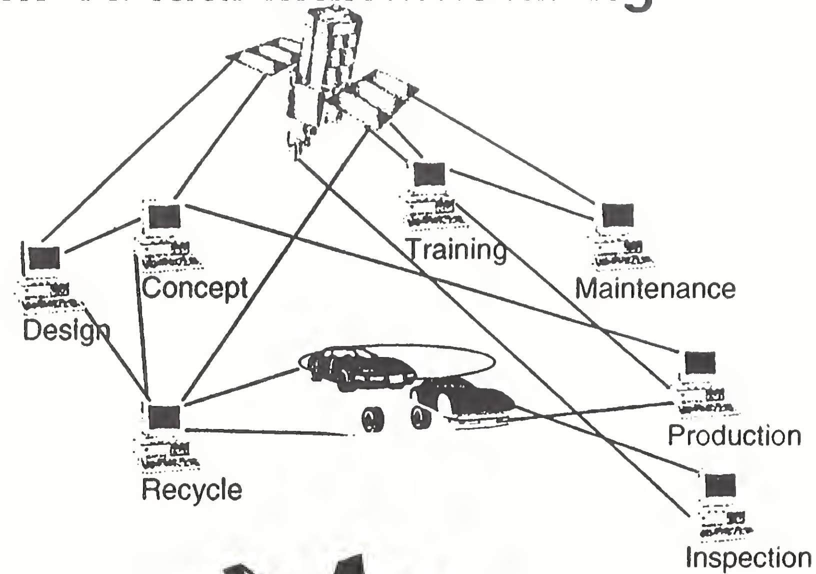
Helping US Companies Improve Competitiveness

Next Manufacturing Paradigm: Virtual Manufacturing

Worldwide Product Data Exchange:



Via Industry-Driven Standards to Ensure Interoperability:

Identify Need > Develop Standard > STEP > Test/ Pilot > Implement

Accelerating & Improving the Standards-Making Process:

NIST

Builds Tools & Utilities
Manages Standards' Development
Builds Integrated Test Beds
Maintains Leadership Role
Leads Conformance Testing
Provides On-Line Repository

NIST

Section 6

National strategic Standards Panel

The Intelligent Transportation System Standards Program

Mike Schagrin

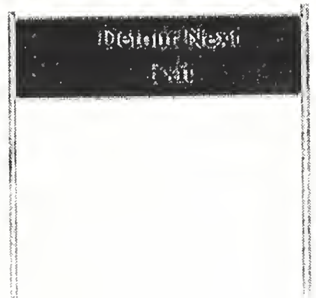
US Department of Transportation
ITS Joint Program Office

ITS is...

- *A set of technologies:*
  - *Image processing*
  - *Sensing*
  - *Wireless communications*
  - *Geo positioning*
  - *Computer information systems*
  - *Robotics*

Applied to Transportation Problems

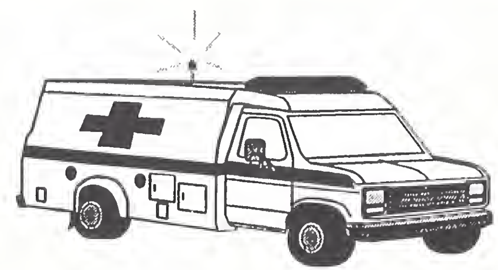
Traffic Management & Control



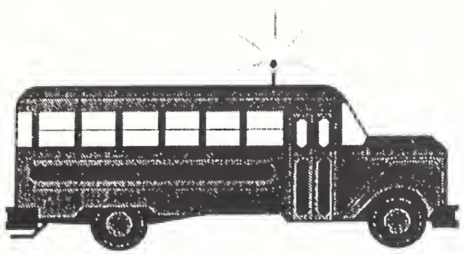
Why:

- Increase "Capacity" on congested streets and highways
- Save Lives

Vehicle Tracking

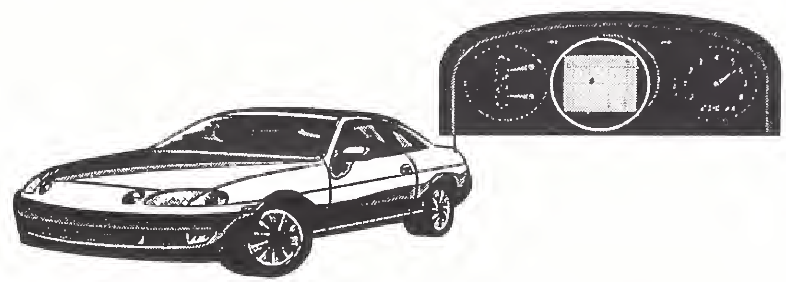


√ Improved Emergency Response

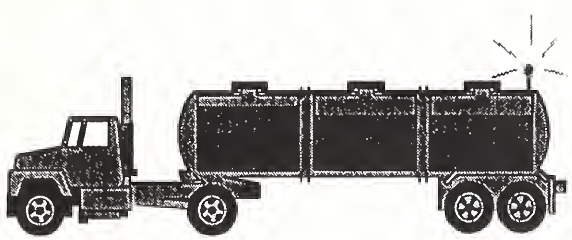


√ Public Transit Productivity

In Vehicle Navigation



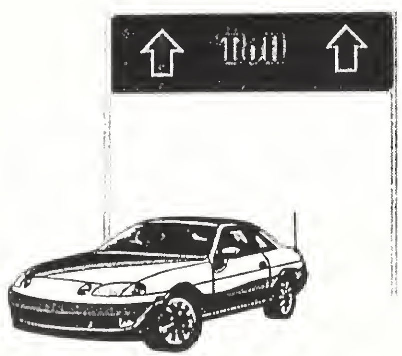
√ Customer Convenience



√ Shipping Productivity

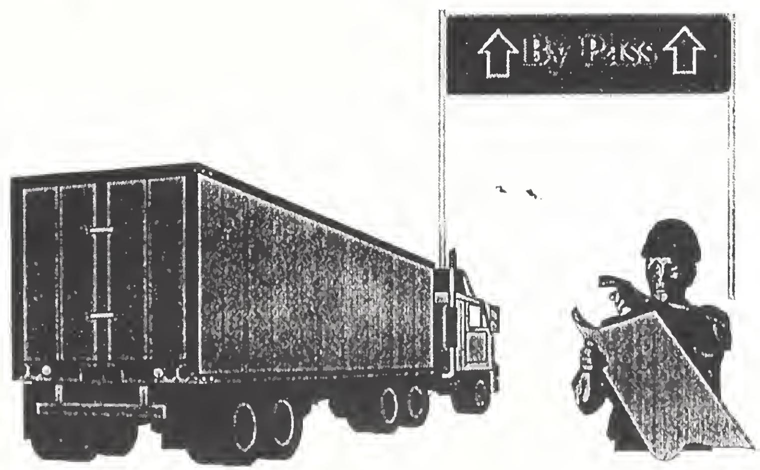
Government Transactions

- ✓ Automatic Toll Collection

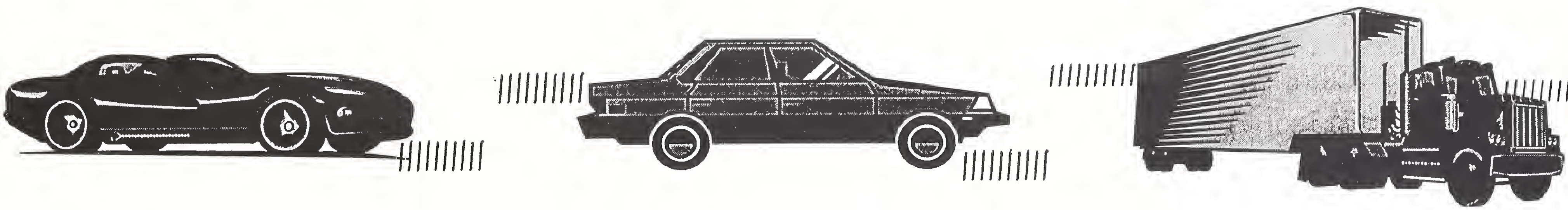


- ✓ Border Crossing

- ✓ Commercial Vehicle Regulation



Vehicle Operations

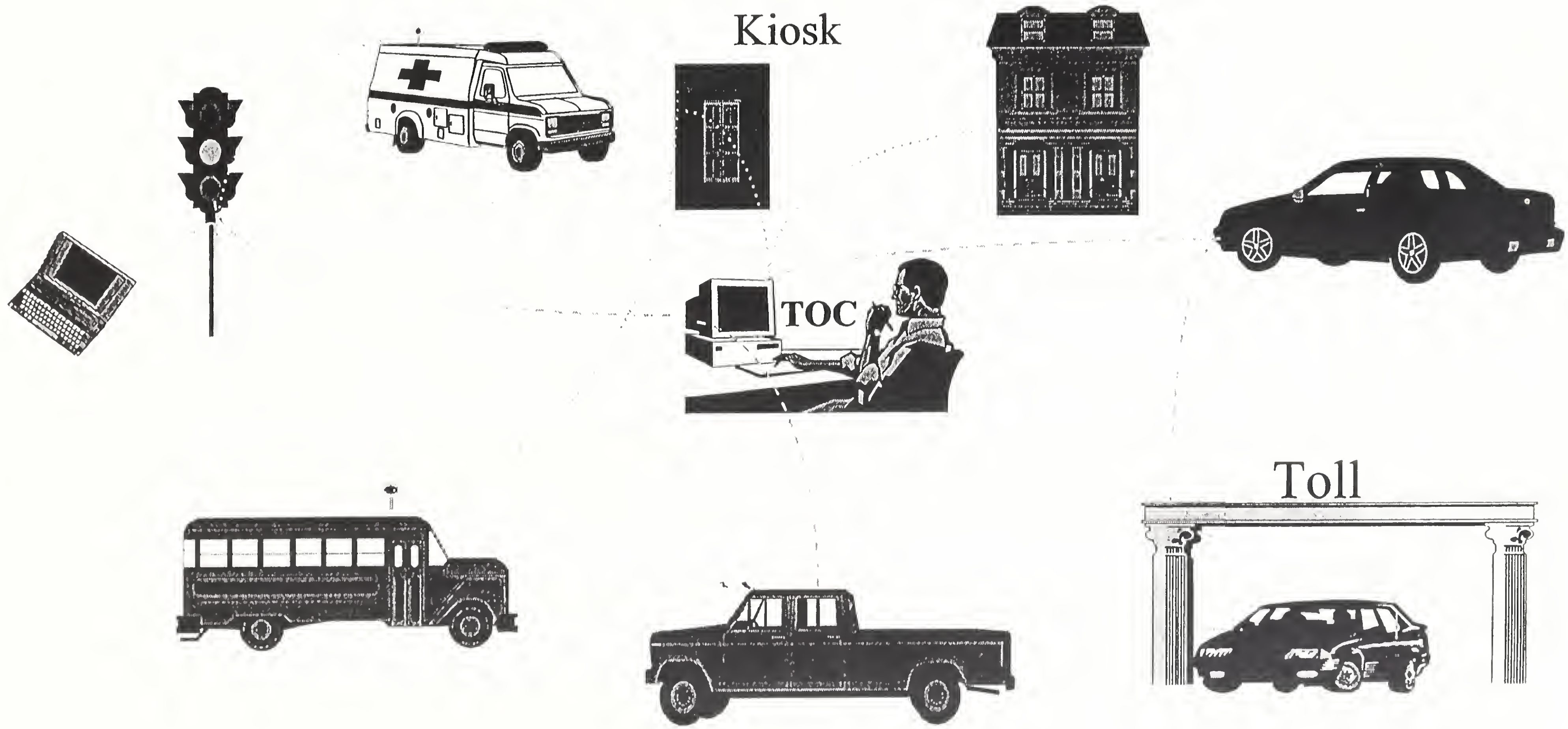


Reduce Fatalities and Accidents

✓ **Crash Avoidance**

✓ **Driver Monitoring**

If We Link The Systems...



Goal

"The Secretary shall develop and implement standards and protocols to promote the widespread use ...of ITS technology,...and shall promote (national) compatibility "

[Intermodal Surface Transportation Efficiency Act of 1991]

Guiding Principles

- Facilitate interoperability
- Provide multi-vendor environment
- Facilitate deployment
- Ensure the safety of the traveling public
- Promote creation of a strong ITS market

Program Structure

- The standards program
  - 5 years
  - Funding support initiated in January 1996
  - Guided by a National Architecture
- 5 standards development organizations
  - To develop non-proprietary, consensus based standards across multiple disciplines
- A strong public/private partnership

Funded SDOs

- The Society of Automotive Engineers (SAE)
- The Institute of Electrical and Electronics Engineers (IEEE)
- The Institute of Transportation Engineers (ITE)
- The American Association of State Highway and Transportation Officials (AASHTO)
- The American Society for Testing & Materials (ASTM)

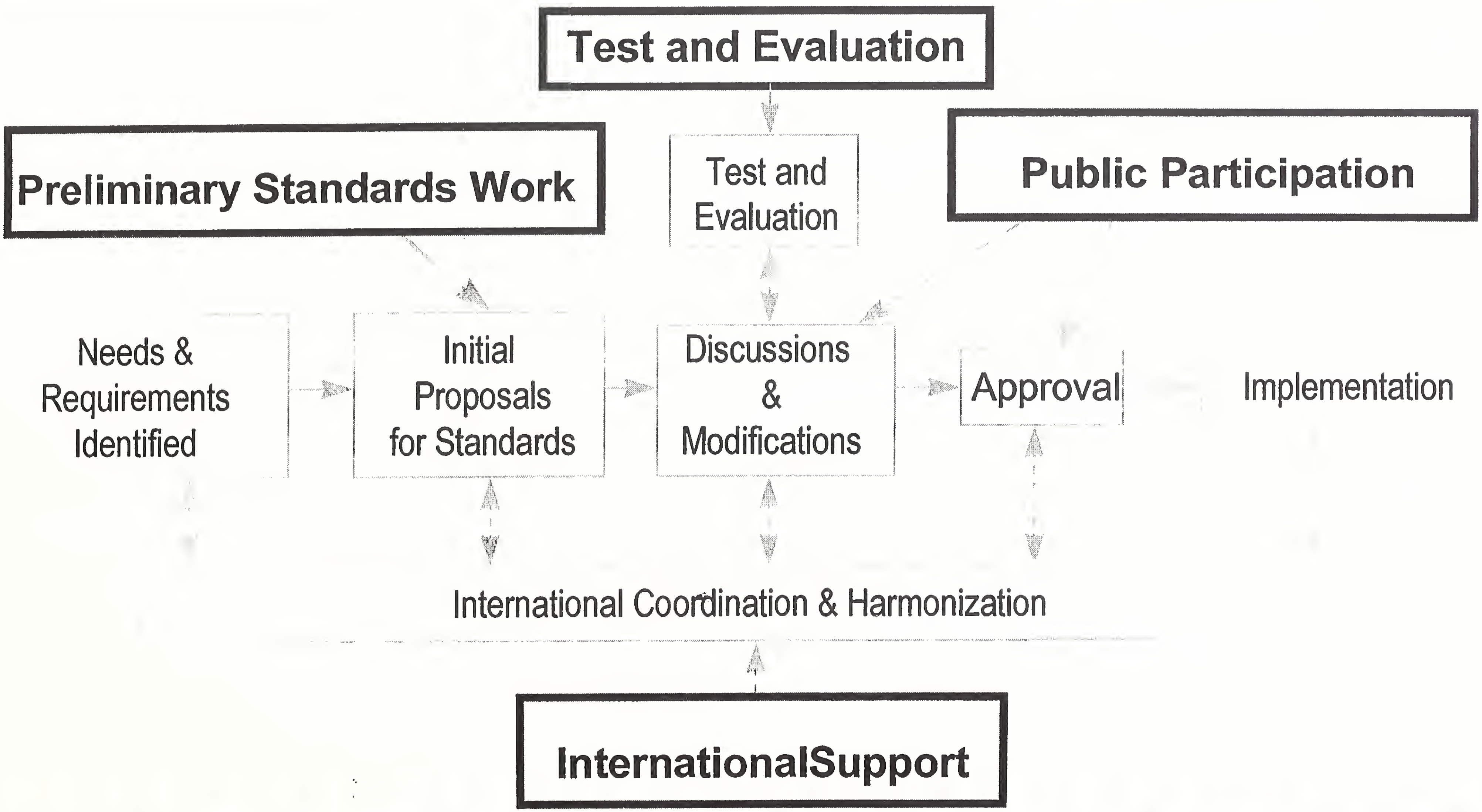
Types of Standards

- *Communications*
- *Data Dictionaries/Message Sets*
- *Formatting*
- *Spatial Data Interchange*
- *Safety and Human Factors*

Areas of Support

- Preliminary Standards Work
- Test and Evaluation
- Public Sector Participation
- International Support

Federal Facilitation



Priorities & Oversight

- Priorities established early
  - ITS America and US DOT surveyed the community for priorities and timing
  - Formed basis for a 5 year plan
- Coordination via the ITS America Council of Standards Organizations

Current Status

- *10 standards approved*
- *Over 40 additional efforts underway*
- *Approximately 20 standards, total, by the end of the year*
- *Perhaps as many as 100 over the next few years*

Issues

- *Coordination among activities*
- *Continued volunteer support*
- *Training/awareness*
- *Testing and integration*
- *Data registration*
- *Rulemaking*

A SUCCESSFUL DHHS-ANSI SDO PARTNERSHIP

J. Michael Fitzmaurice, Ph.D.

Agency for Health Care Policy and Research

September 8, 1997

AHCPR's Interest in Standards

- Research into what works in the community's practice of medicine and how much it costs requires large data bases of uniform, accurate clinically meaningful patient data
- Improving direct patient care requires interoperability of health information systems and exchange of accurate patient care data

The Problem

- The U.S. health care industry lags other U.S. industries in the use of information technology.
- Cost savings and quality improvement in health care can be achieve by greater uniformity, accuracy, and automation of health care data.

Solving the Problem

- How do we do it?
  - Promote coordination
  - Share expertise
  - Use standards in Federal programs
  - Learn from international experiences

U.S. Standards

- De facto
- Government regulation
- American National Standards

A Congressional Solution

- Industry asked Congress for uniform implementation of existing standards
- Congress passed HIPAA,with an Administrative Simplification section
- DHHS is directed to adopt standards for specific administrative health-care electronic transactions
- Secretary adopts by Feb. 1998; Industry adopts by Feb. 2000.

ANSI HISB

- Evolved from the temporary ANSI Healthcare Informatics Standards Planning Panel, created in 1991
  - Chair, Clement McDonald, MD
  -
- HISB was created 1995, a permanent panel
  - Chair, C. Peter Waegemann
- Supported by AHCPR since its creation

ANSI HISB

- An open, public forum for the voluntary coordination of healthcare informatics standards among all U.S. standards developing organizations
  - 34 members
  - More than 60 other participants
- International coordination of healthcare informatics standards with U.S.

HISB Members

- ASC SDOs
- Other SDOs (ACR/NEMA)
- Middleware SDOs
- Consortia/Assns
- Government
- Industry

ANSI Accredited SDOs

- ADA
- ASTM E1131
- HIBCC
- HL7
- IEEE
- NCPDP
- X12
- NEMA (ACR)

Consortia/Assns

- NUCC
- NUBC
- CPRI
- ANA

- HOST
- CORBAMed
- WEDI

Government

- AHCPR
- HCFA
- NLM
- DoD
- VA
- FDA
- CDC
- NCI

Industry

- Vendors
- Computer Companies
- Network Companies
- Others

The Work of HISB

- Technical Coordination
  - Vocabulary, IDs, and Data sets
  - Security
  - Frameworks and Models
- International Coordination
- Publicity and Education
- Legislative and Regulatory

Specific Activities

- HIPAA Inventory
- ISO Technical Committee on Healthcare Informatics
- Dispute Resolution

HIPAA Standards

- PL 104-191, Health Insurance Portability and Accountability Act of 1996
- Signed by President Clinton on August 21, 1996
- Standards are required for all health plans, providers, & clearinghouses who conduct 10 transactions electronically.

HIPAA Requires

- Secretary must adopt standards for 10 electronic health admin. transactions.
- Unless no existing standards, or substantial cost reductions will result, Secretary must adopt "a standard that has been developed, adopted, or modified by a standard developing organization."

10 Transactions

- Claims/Encounter
- Claims Attachments
- Enrollment
- Eligibility checking
- Remittance Advice
- Premium Payments
- First report of injury
- Health claim status
- Referral Authorization
- Coordination of benefits

HIPAA Standards

- Secretary must also develop standards for supporting standards
  - Identifiers
  - Code Sets
  - Security
  - Electronic signatures
- Secretary's adoption--by Feb. 1998

HISB's Response

- Inventory SDO standards pertinent to HIPAA
- Sent to the Secretary of HHS: Oct. 1996
- Map the standards to the requirements of HIPAA
- Sent to Secretary of HHS: Feb. 1997

Inventory of Health Care Information Standards

- Executive Summary
- Transaction Standards
- Supporting Standards
- Appendices
  - Templates
  - Activities to promote inter-operability
    - Frameworks/Architectures, and Models
    - Other (CPRI, Wright State, ASTM)

Outline

- Transactions Standards
- Supporting Standards
  - Code sets
  - Unique identifiers
  - Security, safeguards, and electronic signatures
- Appendices

Template

- Category
- SDO
- ANSI Accredited?
- Name of Standard
- Contact person
- Description of Std
- Readiness
- Indicators of market acceptance
- Level of specificity
- Relation to other Standards
- Identifiable costs

How was the Inventory Used?

- In HHS, six implementation teams were formed to develop standards' recommendations for the Secretary
  - Information and Cross-cutting Implementation Team
  - Five others
- Each of the five teams used the Inventory as their starting point

Status of Standards Adoption

- Transactions (10)
  - All transactions except claims - X.12N
  - Pharmacy claims - NCPDP
  - Medical, dental & institutional - X.12/837
  - Claims attachments - X.12/275, HL7 (decision next year)

Status of Standards Adoption

- Identifiers
  - Provider - National Provider Identifier (HCFA)
  - Payer - PayerID (HCFA)
  - Employer - EIN or SSN of salary source?
  - Individual - SSN, modified SSN vs. new health ID??

Status of Standards Adoption

- Coding
  - Diagnostic - ICD-9-CM -> ICD-10-CM in 2001
  - Procedures - ICD-9-CM Vol. 3 + CPT-4 + HCPCS -> ICD-10-PCS or CPT-5 or alternative uniform procedure coding framework in 2002 or 2003
  - Security standards - ASTM guidelines and policies, NCVHS recommendations
  - Electronic signatures - ASTM?

Benefit to DHHS

- Inventory of options for legislatively mandated standards
- Source of business models
- Source of implementation guides
- Quick review, comment, and feedback from SDOs and users
- Brings government into the standards process

Benefit to DHHS

- Better dissemination from the existing infrastructure of SDO meetings
- Industry buy-in
  - More rapid adjustment and adoption
- Standards that will be used
- Potential for future collaboration
  - Administrative simplification
  - Clinical health data standards

Issues

- Testing standards
- Certifying systems and networks\
- Support for maintenance and updating standards
- Privacy protection for individually identified health information
- Composite national data dictionary

Issues

- Training and awareness of health data standards
- Continued volunteer support of standards

FDA Recognition of Consensus Standards - Where We Are

Donald Marlowe

Director

Office of Science and Technology

Center for Devices and Radiological Health

CDRH Center for Devices and Radiological Health

U. S. Food and Drug Administration

Success Stories

- ISO 9000 used as the basis for the FDA Quality Systems Regulation
- ISO/AAMI Sterilization Standards
- ISO/AAMI Heart Valve Standards
- ASTM/ISO Specifications for Implant Materials
- ISO/AAMI Biocompatibility Standards
- IEC 60601 Safety of Electromedical Equipment

Accreditation of Certifiers

- Any Certification Body that operates and is accredited under applicable ISO/IEC Guides
- Others after Scrutiny by FDA

THE CONCEPT -

Certification to Consensus Standards is Sufficient Evidence of Safety in Regulatory Submissions

- Declaration of Conformity
- Independent Certification

1996 Standards Activity

- 480 Standards Development Efforts
- 223 CDRH Staff Members Active
- 30 FTEs Committed
- 36 National and International SDOs Engaged

Standards at the FDA

Gary Fischman, Ph.D.
Division of Mechanics and Materials Science
Office of Science and Technology
Center for Devices and Radiological Health
US Food and Drug Administration

Why Bother with Standards?

- Standards can increase the comparability of tests
- Standards can add confidence to test results
- Standards can decrease the cost of evaluation for both the government and industry
  - Material specifications can minimize testing needs for use in a device
  - Standard test methods make results easier to understand and correlate
  - Performance standards make it easier to assess effectiveness of a device

The Present

- At present, the Center puts forth a great deal of effort to develop standards
- There is not yet a coordinated effort towards standards use in the evaluation of devices
  - Standards usage in the evaluation process is dependent upon evaluator and branch.
- Standards development is based on interest level of those working on standards

Case Study - Abrasion of Coatings (I)

- History
  - 1995 - FDA issued a required postmarket surveillance (RPS) of devices with certain "thermal sprayed coatings"
  - 1995 - a guidance for challenging the RPS was issued
    - 3 tests were given for the challenge
    - unsure of our comfort level with these tests
  - 1995 - A very specialized somewhat expensive test was developed by a medical implant company

Case Study - Abrasion of Coating (II)

- It was in the FDA's best interest to determine their level of comfort with at least one of the three tests.
- A likely candidate test had to be chosen.
  - Many companies were already using a commercial test device
    - The device seemed simple in operation
    - Other tests considered were either expensive or had a large degree of variation in material properties (e.g., bone)
  - The commercial test device was chosen

Case Study - Abrasion of Coatings (III)

- Test Development
  - A program was developed to assess the use of this device to raise comfort level on comparative values for abrasion resistance
  - From the results a draft standard was developed
  - The draft standard is being incorporated into an abrasion standard in F04 of ASTM.

What will CDRH do with Standards

- CDRH will attempt to replace its submission guideline tests with standards wherever possible.
  - Simplify the approval process
  - Lower the cost of evaluation

Changes in Standard Development Strategy in CDRH

- In reengineering, it was decided that CDRH needed a new model for standards development and use.

Standards development in CDRH should:

- Meet center needs
- Provide resource savings when used in regulatory processes (e.g., Product Review)
- Maintain public health protection.

Standards as a Major Building Block

- Whenever possible and reasonable, standards will be used as criteria for evaluation.
- If the need arises, CDRH will develop standards that can be used for device evaluation.

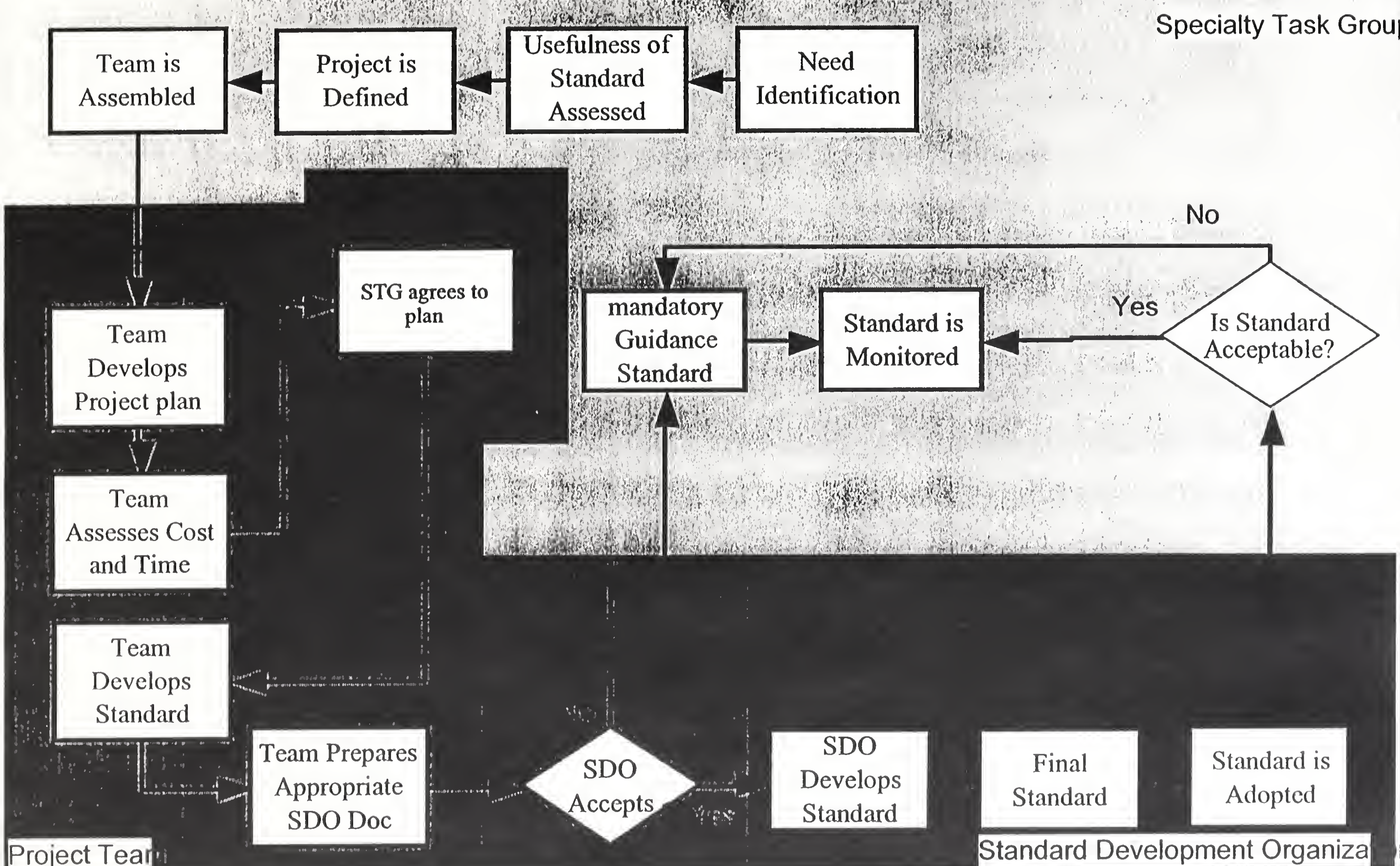
Standards Development at CDRH

- Standards are envisioned to be needs based and team developed
- 13 Specialty Task Groups have been selected to assess needs and facilitate the development of standards within their specialties.

Specialty Task Groups

- In Vitro Diagnostics
- Ophthalmology
- Cardiovascular/Neurology
- Anesthesiology
- Orthopedics/Physical Medicine
- Software
- General Hospital and Plastic Surgery
- Dental/ENT
- Electromagnetic Compatibility
- Sterility
- Biocompatibility
- Obstetrics-Gyn/ Gastrointestinal

Standards Task Flow



CDRH Center for Devices and Radiological Health

U. S. Food and Drug Administration

Specialty Task Group Role

- Develop a dynamic global plan of standards needs within specialty
  - Identify standards that can be of use
  - Identify standards activities in which we should be part
    - Recommend allocation of funds for attendance of liaison
  - Identify standards which need development
    - Facilitate the formation of Project Teams to form standards
    - Help form the team

Project Teams

- When an STG believes a standard is needed, a Project Team is formed
  - The project team produces a project plan and cost estimate
  - If the project team and STG can agree to the project, the project is then executed by the project team
    - The project team further assesses the need for the standard
    - If necessary the team may develop a standard
      - Test development
      - Standard writing
      - Presentation to SDO

Expectations

- Cost and role of standards at CDRH will rise
- Use of standards for regulations at CDRH will rise
- Cost of evaluation will decrease

Section 7

Biographies of Moderators and Panelists

Belinda L. Collins, Ph.D
Director, Office of Standards Services
National Institute of Standards and Technology

Dr. Collins is the Director of the Office of Standards Services at the National Institute of Standards and Technology (formerly National Bureau of Standards). The Office of Standards Services provides policy support for standards and conformity activities for regulatory, procurement, and trade agencies of the Federal Government. The Office administers five programs: Global Standards, Laboratory Accreditation, Standards Conformity, Standards Information, and Technical Standards Activities.

Dr. Collins also chairs the Interagency Committee on Standards Policy (ICSP) for the NIST Director. A researcher at NIST from 1984 to 1995. She received her B.A. in experimental psychology from Mary Washington College, and her M.A. and Ph.D. in experimental psychology (vision) from the University of Virginia. Dr. Collins has authored numerous technical publications in the area of lighting and human response. She is a Fellow of the Illumination Engineering Society of North America as well as Society Vice President for Education, and a recipient of the NIST Bronze Medal.

Sergio Mazza
President and Chief Executive Officer
American National Standards Institute (ANSI)

Sergio Mazza was named President and Ceo of the American National Standards Institute (ANSI) by its Board of Directors on November 29. 1993.

ANSI is a not-for-profit membership organization that brings together organizations from both private and public sectors dedicated to furthering U.S. and international voluntary consensus standards and conformity assessments. ANSI accredits national standards developing organizations and approves American National Standards. It is the sole U.S. representative to the International Organization for Standardization (ISO) and the International Electrotechnical Commission (IEC), via the U.S. National Committee.

Before accepting the position of ANSI President, Mr. Mazza was active as a software entrepreneur, most recently as President of DS Group, Inc. Mr. Mazza's corporate career included the position of President of Memorex Computer Supplies, where he also served on the boards of Memorex Technologies, Inc., U.S.A. and Memorex Copal Corp., Japan. Prior to that he was President of Memorex U.S.A.

Mr. Mazza holds a B.S. degree in economics with a dual major in finance and multinational enterprises from the University of Pennsylvania's Wharton School. He speaks four languages fluently, and has lived in seven different countries.

Richard E. Feigel, Ph.D
Vice President, Engineering
Hartford Steam Boiler Inspection & Insurance Co.

Dr. Feigel is responsible for engineering and corporate quality initiatives in service delivery, training, risk evaluation and loss prevention. He assists internal and external clients in defining and implementing cost effective risk management and engineering programs. He has over 20 years experience with his company with expertise in quality assurance, ASME codes and standards and risk assessment. His previous experience includes pressure vessel construction, welding, radiography, quality assurance.

Professional Designation(s): Fellow, American Society of Mechanical Engineers

Professional Affiliations: American Society of Mechanical Engineers, Member, American Welding Society, Member

Professional Activities:

- Chairman and Senior Vice President, ASME Council on Codes and Standards
- Past Chairman, ASME Board on Council Operations
- Past Vice President, ASME Board on Pressure Technology Codes and Standards
- Welding Research Council, Board of Directors
- ASME Boiler and Pressure Vessel Code Main Committee
- ASME Code for Pressure Piping, Past Chairman

Dr. Feigel has numerous copyrights, patents and publications.

Howard L. Hime
Chief, Office of Standards Evaluation and Development
U.S. Coast Guard

Howard L. Hime is Chief, Office of Standards Evaluation and Development for the U.S. Coast Guard. This Office is responsible for development of all Coast Guard regulations relating to marine safety and environmental protection.

Mr. Hime is a registered Professional Engineer and certified nuclear power plant engineer. He has been responsible for the design of nuclear power plants, manned deep ocean simulators, diving systems, offshore structures, and advanced weapons development.

Mr. Hime has been with the U.S. Coast Guard for 20 years and has been involved in standards development for 28 years in the fields of boilers, pressure vessels, materials, welding, and ships and marine technology. Mr. Hime has received ASTM's coveted John Hass Memorial Award and ASME's Dedicated Service Award for his outstanding leadership and support for standards development. Mr. Hime has also received the National Society of Engineers Engineer of the Year award for his efforts in developing and promoting the use of standards. And recently, Mr. Hime was awarded the Vice President's Hammer award for his achievements in regulatory reinvention.

Richard B. Felder
Associate Administrator
Office of Pipeline Safety
Department of Transportation

Richard Felder is Associate Administrator for Pipeline Safety at the U.S. Department of Transportation's Research and Special Programs Administration. The Office of Pipeline Safety administers the Federal regulatory program to assure safe and environmentally sound transportation of natural gas, petroleum, and other hazardous liquids by pipeline. He is also responsible for developing regulation and other approaches to risk management to assure safety in design, construction testing, operation maintenance and emergency response of pipeline facilities.

Mr. Felder has been a force for regulatory change in government and the private sector. He managed both trucking and railroad programs at the Interstate Commerce Commission (ICC) where he implemented the Staggers Rail Act and the Motor Carrier Act of 1980. Mr. Felder also served as Vice President for Government Affairs at TransAmeria Interway, acting as both corporate officer and representing the company's interests before executive departments, Congress, and a variety of regulatory agencies. He also served as a partner at the law firm of Amall, Golden and Gregory in Washington where he represented clients on various issues, including railroad and trucking matters.

Mr. Felder holds a bachelors degree from Cornell University, and J.D. from New York University School of Law. He has taught regulatory management at the University of Wisconsin, and is currently involved in designing a regulatory curriculum at American University's School of Public Affairs.

Mr. Felder currently resides in Bethesda, Maryland, with his wife, Deborah, and two sons, Jon and Jeff.

Gilbert C. Millman
U.S. Nuclear Regulatory Commission

Mr. Gilbert (Gil) Millman, Program Manager, Codes and Standards, joined the NRC, while it was still the Atomic Energy Commission (AEC), in 1974. His heavy involvement in the standards process started at that time when he was assigned to provide staff support for NRC participation on the ASME Section XI Subcommittee on Nuclear Inservice Inspection, the ASME Boiler and Pressure Vessel Committee, and the ASME Board on Nuclear Codes and Standards. Mr. Millman is now the authorized NRC representative on these high level committees, which focus on, respectively, technical, consensus, and policy matters. He has been, in the past, responsible for preparing and issuing rulemakings that incorporate, by reference, the ASME code into the NRC regulations. He is presently participating on an NRC task group that is developing an implementation plan to respond to commission direction regarding the use of consensus standards.

Colin Church
Consumer Product Safety Commission

Colin Church is the Voluntary Standards and International Activities Coordinator for the U.S. Consumer Product Safety Commission. He is Chairman of the Regulatory Agencies Work Group, Interagency Committee on Standards Policy; serves on ANSI's Board of Directors, Government Member Council, Consumer Interest Council and Executive Standards Council; is a member of ASTM's Executive Subcommittee of the Committee on Consumer Products; and is a member of UL's Consumer Advisory Council.

Mary C. McKiel
Director, Standards Network
U.S. Environmental Protection Agency

Currently, Mary McKiel is the Director of EPA's Standards Network, Mary has been with EPA for six years. Mary began her career in 1976 as a chemist with the National Archives. From 1981 to 1992, she held several senior positions with the Federal Supply Service of the General Services Administration (GSA), including Director of Quality Standards and Director of Environmental Policy.

A long-time advocate of voluntary standards, Mary has served for eight years on the Board of Directors of the American National Standards Institute (ANSI). She is past Chair of the ANSI Government Member Council and past President of the International Coalition for Procurement Standards.

Since coming to EPA, Mary has established the first standards network of its kind at the Agency. She also represents EPA on the U.S. Technical Advisory Group for the Environmental Management Standards Technical Committee (TC 207) of the International Organization for Standardization (ISO).

Steven D. McNeely
Office of Underground Storag Tanks
Environmental Protection Agency

Steven D. McNeely is an Environmental Protection Specialist with EPA's Office of Underground Storage Tanks (OUST). During his ten years in OUST, he has served as Liaison Officer for EPA Regions 4, 5, 6, 8 and, is currently coordinating with Region 2 to develop their State Underground Storage Tank programs. As a member of OUST's Corrective Action Technologies Team (CATT), he has fostered a wide range of projects to improve the understanding and use of alternative remedial technologies applied at petroleum release sites. He also serves as the Project Officer managing EPA's Risk-Based Corrective Action (RBCA) Training Cooperative Agreement with ASTM.

On February 26, 1997, Mr. McNeely received a Gold Metal from EPA Administrator, Carol Browner, for managing the Partnership in RBCA Implementation (PIRI) - a public-private partnership which fosters RBCA training and implementation in State Underground Storage Tank programs.

Caroline B. Purdy, Ph.D
Program Manager for Characterization, Monitoring, and Sensor Technology Integrated Program
U.S. Department of Energy

Dr. Purdy is the Program Manager for Characterization, Monitoring, and Sensor Technology Integrated Program in the U.S. Department of Energy's Office of Technology Development within the Office of Environmental Management (EM). She is responsible for establishing and managing a national applied R&D program to develop technologies for characterizing the waste and waste environments throughout the DOE complex, and for developing sensors for subsurface characterization, for site closure and compliance monitoring, and for process monitoring of waste treatment.

She directs a program of research, development, and demonstration of advanced environmental sensors and characterization techniques. The program has a large budget and includes technologies such as: geophysical sensors, laboratory and field chemical sensors and instrumentation, contaminant transport modeling, data fusion, nondestructive assay, and radiological sensors. Characterization technologies are primarily applied to high-level waste in underground storage tanks, mixed waste treatment, decontamination of DOE facilities, locating and measuring concentration levels in contaminant subsurface plumes, and monitoring remediation, contaminant transport and barrier integrity at landfills.

Education: Ph.D in Chemistry, 1991, University of Maryland. Geochemistry with a concentration in nuclear analytical methods.

Geochemist with primary emphasis on using radiouclides produced in the atmosphere as tracers to delineate ground water movement.

Areas of expertise:

- Understand the atmospheric and subsurface production mechanisms of rare isotopes used as ground water tracers.
- Using cosmogenically produced isotopes as tracers to identify ground water recharge zones, ground water flow patterns, and dating the ground water.
- Using geochemical modeling programs to predict ground water chemical composition.

Gregory E. Saunders
Deputy Director, Acquisition Practices
Department of Defense

Gregory E. (Greg) Saunders is the Deputy Director of Acquisition Practices in the Office of the Assistant Secretary of Defense for Economic Security. His principle focus is on implementing the Department's Specification Reform initiative, developing policies and procedures to enable DoD components to buy more commercial products and nondevelopmental items (NDI), and to use more commercial buying practices. As the OSD focal point for advocating use of NDI, he served on two Defense Science Board Studies on Commercial Components, both chaired by Secretary Perry, and was responsible for DoD's implementation of their recommendations; He is working with the Defense Standards Improvement Council on reform of the Military Specifications and Standards program; has testified before congress on DOD's progress implementing a statutory preference for NDI; and has served on numerous study groups.

He oversees the Defense Standardization program and is responsible for policy governing such issues as the development and use of Qualified Manufacturers Lists, use of industry standards, development of performance standards, and others.

Mr. Saunders came to his current position in 1986 from the Defense Standardization Program Office where he was responsible for the DoD's program to adopt and use standards produced by voluntary standards organizations and for various other aspects of standardization policy.

He is an engineering graduate of the University of Evansville in Evansville Indiana, serves on the Aerospace Council of the Society of Automotive Engineers, represents the Department of Defense on the American National Standards Institute's Government Member Council, serves on their Board of Directors, and Chairs the Standards and Data Services Committee.

Greg may be reached at his internet address "Saundege@acq.osd.mil"

Mr. James D. Nicolo
Director
Engineering and Technical Services Office
Defense Industrial Supply Center

Mr. James Nicolo has over 36 years of government service with experience ranging from Production Engineering of metal parts to standardization of industrial hardware items. He received his undergraduate degree in mechanical engineering from Villanova University in 1961. In 1976 Mr. Nicolo joined DISC with an initial assignment of managing item standardization programs such as Metrication, Voluntary Standards, Specification and Standards and commercialization of industrial hardware spare parts.

In 1984 Mr. Nicolo introduced the Test and Evaluation Program at DISC and for his achievements in this area he received the Secretary of Defense Superior Management Award.

Currently Mr. Nicolo is the Deputy Director of the Engineering and Technical Services Office at DISC. He has held this position for over 7 years and has been instrumental in fostering a collaborative industry and government approach to optimizing the standardization of industrial hardware spare parts through the specification and standards process.

Bruce L. Mahone
Director, Standardization
Aerospace Industries Association

Bruce Mahone has been working in aerospace standardization since 1989, first as Assistant Manager, Technical Division of the American Gear Manufacturers Association and now as Director of Standardization for the Aerospace Industries Association of America. In his capacity as Executive Secretary of AIA's National Aerospace Standards Committee, he is responsible for the largest collection of trade association standards in the United States. He also serves as Secretary of the primary international forum for aerospace standardization, ISO Technical Committee 20. Standards he has worked on run the gamut from electrical and mechanical parts to materials, lubricants, and style manuals. A member of the Standards Engineering Society, Mr. Mahone also facilitates government acquisition reform as it pertains to aerospace manufacturers through AIA's Early Warning Project Group. In addition to his contributions to the World Standards Day Planning Committee, his recent activities have strongly emphasized coordinating industry views on national space policy and converting military specifications to commercial standards.

He completed his mechanical engineering degree in 1976, with an emphasis on aerospace systems.

Howard M. Bloom
Deputy Director
Manufacturing Engineering Laboratory
National Institute of Standards and Technology

Mr. Bloom is currently Deputy Director of the Manufacturing Engineering Laboratory at the National Institute of Standards and Technology (NIST). He has over thirty years of experience in the application of information technology to engineering applications with the last 16 years specifically in manufacturing engineering. At NIST, he has directed research and development of Computer Integrated Manufacturing (CIM) applications and interface specifications in the areas of design, process planning, production control and the information infrastructure to support these applications (e.g. distributed database systems and factory networks).

He has a driving interest in national research and standards efforts related to the application of information technology for manufacturing, with special interest in the development of product data standards, for which he spent 12 years directing the NIST efforts.

Richard J. (Rick) Serbu
U.S. Department of Energy

Rick Serbu has been the DOE Technical Standards Program Manager since October 1994. He is responsible for overall coordination and direction of the Department's Technical Standards Program and technical standards activities, and integration of these activities into the recently established Department Standards Program. Rick joined DOE in 1990 and was appointed Acting Director of the Safety Inspection Division with responsibility for the Technical Safety Appraisal Component of DOE's Tiger Team Assessments. He subsequently served as Director of the Nuclear Safety Technology Division and, later, Director of the Risk Analysis and Technology Division; in these positions, Rick was active in the 90-2 Coordination Committee, rulemaking, and S/RIDs (EH representative), and had responsibility for EH-30 standards management and management of non-nuclear safety analysis, risk analysis, chemical safety, and natural phenomena hazards mitigation programs. He also served as a core member of the Headquarters Support Group for the Department Standards Committee, and has been instrumental in establishing the Department Standards Program. Rick was also one of the founding members of the EH Policy/Standards Process Improvement Team.

Prior to coming to DOE, Rick worked for the Nuclear Regulatory Commission, Tennessee Valley Authority, and Knolls Power Atomic Laboratory. His work for these organizations was focused in the areas of radiological protection/training, health physics, program management, shift supervision, and development and review of regulatory guidance and standards. He represented the NRC on various standards committees of the Health Physics Society, American National Standards Institute, American Nuclear Society, and American Society for Testing and Materials. Rick is currently a member of the Health Physics Society.

Rick served for over six years as an Air Force Pilot/Aircraft Commander during the Vietnam era. In addition to his combat experience during three Southeast Asia tours, Rick served in the 99th Bomb Wing Standardization and Evaluation Unit. He received his B.A. degree in Chemistry from the State University College in Potsdam, New York.

Michael C. Schagrin
Standards Program Manager
U.S. Department of Transportation

Michael C. Schagrin is the Standards Program Manager for the United States Department of Transportation's Intelligent Transportation Systems Joint Program Office. The U.S. DOT is pursuing an ambitious program of expediting the development of ITS volunteer standards and Mr. Schagrin is responsible for ensuring successful implementation of that program. Prior to joining the U.S. DOT, Mr. Schagrin worked for the U.S. Department of Defense and was responsible for the development and procurement of sophisticated Navy shipboard combat systems.

Mr. Schagrin holds a B.S. im Mechanical Engineering from the University of New Hampshire and an M.S. in Systems Engineering from George Mason University.

Dr. J. Michael Fitzmaurice
Director
Center of Information Technology
U. S. Agency for Health Care Policy and Research
Office of Science and Data Development

Dr. Fitzmaurice is Director, Center for Information Technology, Agency for Health Care Policy and Research. He joined the Public Health Service in 1987 as Director of the National Center for Health Services Research and Health Care Technology Assessment, coming from the Health Care Financing Administration where he was Acting Director, Office of Research. Previously, as branch chief in the Office of Research he directed the development of Medicare's Prospective Payment System. Dr. Fitzmaurice received his Ph.D. in Economics in 1972 from the University of Maryland. He has undergraduate degrees from St. Joseph's College (Rensselaer, IN) in Mathematics and in Economics. He is an adjunct Associate Professor in the University College Graduate School, University of Maryland.

He served on the White House Health Reform Task Force, Working Groups on Information Systems and on Administrative Simplification, which made recommendations to Hillary Rodham Clinton, Chair of the Task Force, on the use of information technology in health care reform.

Dr. Fitzmaurice represents AHCPR as a member of the White House Information Infrastructure Task Force (IITF), Committee on Applications and Technology. Currently he is actively involved in developing health information technology research programs at AHCPR and in implementing the requirements of P.L. 104-191 for the Secretary of Health and Human Services to adopt national patient care data standards for selected electronic health care transactions.

Donald E. Marlowe
Director
Office of Science and Technology
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